“INJECTION TRANEXAMIC ACID FOR PREVENTING POSTPARTUM HEMORRHAGE AFTER VAGINAL DELIVERY: ONEYEAR HOSPITAL BASED RANDOMIZED, PLACEBO-CONTROLLED TRIAL”

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ABBREVIATIONS

AMTSL	-	Active Management of Third Stage of Labour
BMI	-	Body Mass Index
CONSORT	-	Consolidated Standards of Reporting Trials
DBP	-	Diastolic Blood Pressure
DOME	-	Department of Medical Education
ECG	-	Electrocardiograph
FDA	-	Food and Drug Administration
FDP	-	Fibrin Degradation Products
g/dl	-	gram/ decilitre
GDG	-	Guideline Development Group
gm	-	gram
Hb	-	Hemoglobin
HELLP	-	Hemolysis, elevated liver enzyme, low platelet
i.m.	-	intramuscular
i.v.	-	intravenous
IUFD	-	Intra Uterine Fetal Demise
JNMC	-	Jawaharlal Nehru Medical College
KAHER	-	KLE Academy of Higher Education and Research center
Kg	-	Kilograms
KLE's	-	Karnataka Lingayat Educational Society
m	-	meter
mg/ml	-	milligram/ millilitre
ml	-	milliliters
PAI	-	Plasminogen Activator Inhibitor

PCV	-	Packed cell volume
PPH	-	Postpartum hemorrhage
RCT	-	Randomized Controlled Trial
SBP	-	Systolic Blood Pressure
tPA	-	Tissue plasminogen Activator.
TXA	-	Tranexamic acid
WHO	-	World Health Organisation
µg	-	microgram

ABSTRACT

Background and objectives- Postpartum blood loss is the inevitable blood loss after the delivery of the baby due to the separation of the placenta. Postpartum hemorrhage is a major cause of maternal mortality, accounting for one quarter of all maternal deaths worldwide.

To study the effect of Injection Tranexamic Acid (TXA) for preventing postpartum hemorrhage (PPH) by assessing the amount of blood loss after vaginal delivery.

Methodology-Randomized placebo controlled clinical trial conducted at KAHER's Dr. Prabhakar Kore Hospital Belagavi, including singleton pregnant women planned for vaginal delivery at term. Eligible study participants were randomized by computer based randomization into 2 groups. Both groups received 10 units prophylactic oxytocin. One group received 1 gram (gm) TXA and the other group received placebo. Primary outcome was assessed by the amount of blood loss measured in a graduated collector bag. Secondary outcome included clinical parameters, laboratory parameters and adverse effects of injection TXA. Statistical analysis between categorical variable was studied using chi-square test. Between group comparison was done using t-test/Mann Whitney U-test and within group comparison was done using Wilcoxon sign rank test. P-value<0.05 was considered statistically significant.

Result: It was observed that incidence of PPH in TXA group and Placebo group was 4.85% and 11.21% respectively and was not statistically significant. In the present study, the mean average blood loss was 250.10 ±133.54 milliliter (ml) in the TXA group as compared to 334.2 ± 141.78 ml in the placebo group with a P value of <0.0001, which was statistically significant.In the analysis of secondary objective it was found that 3.88 % and 93.5 % of the participants in the TXA group and placebo group required blood transfusion

respectively. No participants in this study required arterial embolization or emergency hysterectomy.In the present study, change in Hemoglobin (Hb) in TXA group was 1.48 ± 1.22 gram / decilitre (g/dl) and inthe placebo group it was found to be 1.82 ± 1.20 g/dl , with a P value of 0.0066 which was statistically significant.

Change in packed cell volume (PCV) was 3.51± 3.42 in the TXA group and 5.05 ± 4.18 in the placebo group with a P value of 0.0015 which was statistically significant.

Conclusion In addition to the prophylactic oxytocin administration as a part of theactive management of third stage of labor, an antifibrinolytic like TXA can be used to reduce the postpartum bleeding with no major adverse effects.

Keywords

Postpartum hemorrhage, tranexamic acid, blood loss, vaginal delivery

TABLE OF CONTENTS

Sl. No.	Particulars	Page No.
1.	Introduction	**1-4**
2.	Objectives	**5**
3.	Review of literature	**6-20**
4.	Methodology	**21-24**
5.	Results	**25-43**
6.	Discussion	**44-50**
7.	Summary	**51**
8.	Conclusion	**52-53**
9.	Bibliography	**54-59**
10.	Annexures	
	AnnexuresI: Ethical clearance certificate	60
	Annexures II: Consent form	61-91
	Annexures III: Proforma	92-97
	Annexures IV: Key to master chart	98

LIST OF TABLES

Sl. No.	Table	Page no.
1	Distribution according to maternal age	26
2	Distribution based on gravidity	27
3	Distribution based on gravida score	28
4	Distribution based on body mass index	29
5	Incidence of postpartum haemorrhage	30
6	Incidence of atonic and traumatic postpartum hemorrhage	31
7	Average blood loss in the 2 groups	32
8	Analysis of clinical parameters which include need for postpartum transfusion, arterial embolization and emergency hysterectomy	33
9	Change in lab parameters	34
10	Mean change in pulse rate	37
11	Mean change in systolic blood pressure	38
12	Mean change in diastolic blood pressure	39
13	Incidence of minor adverse events	40
14	Incidence of major adverse events	41
15	Distribution based on duration of hospital stay	42
16.	Use of additional uterotonics	43

LIST OF GRAPHS

Sl. No.	Graph	Page no.
1	Distribution according to maternal age	**26**
2	Distribution based on gravidity	**27**
3	Distribution based on gravida score	**28**
4	Distribution based on body mass index	**29**
5	Incidence of postpartum haemorrhage	**30**
6	Incidence of atonic and traumatic postpartum hemorrhage	**31**
7	Average blood loss in the 2 groups	**32**
8	Analysis of clinical parameters which include need for postpartum transfusion, arterial embolization and emergency hysterectomy	**33**
9 **9A** **9B**	Change in lab parameters Between the group comparison of mean change in Hemoglobin Between the group comparison of mean change in packed cell volume	**35-36**
10	Mean change in pulse rate	**37**
11	Mean change in systolic blood pressure	**38**
12	Mean change in diastolic blood pressure.	**39**
13	Incidence of minor adverse events	**40**
14	Distribution based on duration of hospital stay	**42**
15	Use of additional uterotonics	**43**

INTRODUCTION

Postpartum hemorrhage (PPH) is defined as an "estimated blood loss of more than 500 ml after a vaginal delivery or 1,000 ml after caesarean section, or any blood loss sufficient to compromise hemodynamic stability"[(1)].PPH continues to be an important cause of maternal mortality and accounts for one quarter of all maternal deaths across the globe. Approximately 20-25% of all maternal deaths are attributed to PPH in our country. Incidence of PPH is 3% to 15 % of deliveries worldwide, with an incidence of 2-4 % after vaginal delivery and 6 % after caesarean section in India[(2)]and an incidence of 1.7 % in our hospital. It is a strong indicator of quality of women health care [(3)]. Prevention, early recognition and timely intervention are essential in controlling PPH which is considered an obstetric emergency. Identification of severity of the hemorrhage is necessary as visual estimation of postpartum blood loss can be inaccurate, therefore clinical symptoms and signs should be considered for the assessment of PPH.

Risk factors attributed to PPH include previous history of PPH, primiparity, obesity, prolonged labor, augmented labor, multiple pregnancy, previous caesarean section, excess liquor, and macrosomia. Even women with uncomplicated pregnancy have a substantial risk of developing PPH, thereby makingit necessary for preventing PPH in every pregnancy and in every woman. [(4)]

Active Management of Third Stage of Labor (AMTSL) - involves usage of injection oxytocin before delivery of placenta followed by control cord traction of cord. During delivery as the placenta is separated from the uterus,a series of physiologic and hemostatic changes occur in orderto reduce the bleeding which include myometrial contractions, increased platelet activity and rapid degradation of fibrinogen and fibrin, increase in plasminogen activators and fibrin degradation

products (FDP) due to activation of fibrinolytic system.As already known, use of oxytocin routinely enhances the physiological changes as it is a uterotonic and controls the bleeding. However, to stabilize the hemostatic changes which can potentially cause PPH there is need for prohemostatic agent asboth the coagulation and fibrinolysis processes are implicated in reducing postpartum blood loss.[5]

Evidence regarding administration of ergot alkaloids alone or alongside oxytocin in preventing PPH is insufficient in third stage of labor.Administration of oxytocic's or using more than one oxytocic has not proven to significantly reduce PPH and the need for postpartum blood transfusion.

Blood loss frequently leads to transfusion of allogenic blood products, which render the patients to increased risk of transfusion related adverse events which include transfusion reactions, errors in transfusion, febrile nonhemolytic transfusion reactions, blood borne infections. Concerns about blood safety, ongoing blood shortages and increasing blood bank service costshave created interest in reducing transfusion requirements in delivery.

It is beneficial to treat underlying cause of obstetric hemorrhage which may include atonic uterus, retained placental bits or genital trauma.Obstetric emergencies such as abruption, placenta praevia,ruptured uterus, retained placenta, adherent placenta, vaginal and cervical trauma, uterine inversion are the reason for thelarge number of maternal deaths whereas uterine atony accounts to only 6.4 % of all maternal deaths [8]. This emphasizes on the need for a hemostatic agent in controlling bleeding in vaginal delivery along with uterotonics.

Across the globe management approaches of PPH are directed by availability of the resource and include mechanical methods, bimanual compression, tamponade, antishock clothing, administration of intravenous fluids, blood and blood products,

embolization, and pharmacological agents. Historically, most often used in treatment of PPH have been uterotonics with a mechanism of action that facilitated by uterine contraction, as atonicity of uterus was believed to be the underlying trigger. Uterotonics are often commonly used for mitigation of PPH. Oxytocin,is considered as the first lineagent whereas methylergonovine and prostaglandins are used as supplemental uterotonics. [6] However, the pathophysiology of severe PPH includes coagulopathy, and more recently, injection TXA with its antifibrinolytic properties, is gradually being utilized worldwide to manage PPH.

In the hemostatic process, rapid coagulation takes place in a damaged vessel by the building a tight net of fibrin and the fibrinolytic system eliminates the fibrin deposits which may induce permanent vascular occlusion during vascular repair. The complex equilibrium between the coagulation and the fibrinolytic processes maintains an intact vascular structure.[4]TXA , an antifibrinolytic was first used for severe menstrual bleeding , invented by the Japanese in 1960. Widespread trials across the globe have shown that TXA used in trauma and obstetrics have reduced the mortality due to bleeding by1/3rd of the patients.TXA is widely and commonly used as anefficient agent for blood loss reduction in various medicinal fields.TXA, a potent antifibrinolytic agent acts on theplasminogen molecules byblocking their lysine binding site. TXA has the ability to improvepatient's ownhemostatic and coagulation mechanisms. TXA works within 2-3 hours after administering orally, and works immediately after intravenous(i.v) administration, with a half life of 2 to 10 hours. Excretion of the drug isby the kidneys.[5]TXA is easily available, convenient to use, affordable, easy to be administered, and can also be effectively added in the routine management of deliveries and is thus potentiallya valuable addition both for the treatment and prevention of PPH[1]. TXA decreases need for transfusion in patients of

elective surgery, reduces mortality in bleeding patients and menstrual bleeding in women with menorrhagia.[7]

Therefore with prophylactic oxytocin administration in the third stage of labor, an antifibrinolytic can be used toenhance patients own haemostatic mechanism and prevent bleeding.

AIMS AND OBJECTIVES

Primary objective

To study the effect of tranexamic acid for preventing postpartum hemorrhage after vaginal delivery.

Secondary objective

- Clinical

  -Need for postpartum transfusion (until discharge)

  -Need for arterial embolization and emergency hysterectomy for PPH.

- Laboratory

  – mean change in peripartum hemoglobin

  – mean change in peripartum packed cell volume

- Adverse effects

  - To know the minor and major adverse effects of Injection TXA

    Minor adverse effects

    - Nausea
    - Vomiting
    - Dizziness

    Major adverse effects

    - Deep vein thrombosis
    - Pulmonary embolism diagnosis confirmed by radiological examination
    - Myocardial infarction – diagnosis confirmed by Electrocardiograph.
    - Seizure episodes
    - Renal failure needing dialysis.

REVIEW OF LITERATURE

PPH continues to be the leading cause of maternal mortality in developing countries. In a confidential review regarding maternal deaths in South Africa, PPH was the cause of 383 maternal deaths. Of these about 17 % of the deaths were attributable to uterine atony which was well controlled by the use of uterotonics. Other causes of maternal death due to PPH included uterine rupture, retained placenta, uterine inversion and trauma to genital tract. [9]

Diagnosis of PPH is uncertain and often based on incorrect assessments of blood loss. In addition, average blood loss at birth often reaches 500 ml or 1000 ml, and the signs of haemorrhage or blood loss can be masked by the usual rise in plasma volume that occurs during pregnancies. The suggested alternative measures for identifying and diagnosing PPH include changes in haematocrit, transfusion needs, rapid blood loss, changes in vital signs, all complicated by the acute nature of the disease. PPH is also graded as primary, occurring within 24 hours of birth, or secondary occurring more than 24 hours after birth to a postpartum period of upto 12 weeks.[10]

Severe bleeding requires blood transfusion. Blood and blood products are limited essential resources, and need to be used vigilantly. The most effective strategy to minimize bleeding is to improvise surgical and anaesthetic techniques. The most thoroughly tested drugs as hemostatic agents include the antifibrinolytic lysi ne analogues which include aminocaproic acid and tranexamic acid. [11]

Antifibrinolytics drugs, are used as inhibitors of clot breakdown and can be administered as intravenous, intramuscular(i.m), oral, sublingual, buccal and

topicalroute. TXA has proven to reduce the risk of haemorrhage in surgery, bleeding in trauma patients with treatment as early as possible being more effective. TXA can minimize blood loss in women with severe menstrual bleeding. TXA is currently used for primary PPH care if oxytocin and other uterotonics do not stop bleeding or if bleeding is due to trauma.[11]

Various pharmacokinetic studies suggest that TXA has an oral bioavailability of 1/3rd with the peak plasma dose being reached at about 3 hours after drug administration. It has been highlighted in both the CRASH 2 trial and WOMAN study that TXA needs to be given as early as within 3 hours from time of onset of trauma.[10]

Coagulation and Fibrinolysis

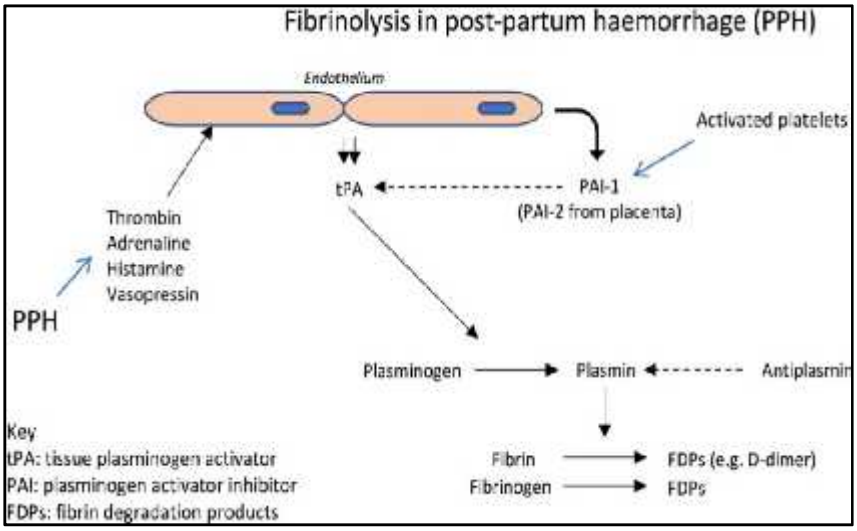
Any injury to vascular endothelium is sealed by the fibrin produced by activation of coagulation system, whereas the removal of these fibrin deposit after the homeostasis is achieved by fibrinolytic mechanism thus maintaining a state of dynamic equilibrium keeping the vascular compartment patent.[36]

There are certain changes occurring in coagulation system during pregnancy and puerperium. Plasma concentration of clotting factors increase, rendering it a hypercoagulable state. However post placental separation, the fibrinolytic mechanism dominates the coagulation mechanism which reduces the coagulation potential of blood.

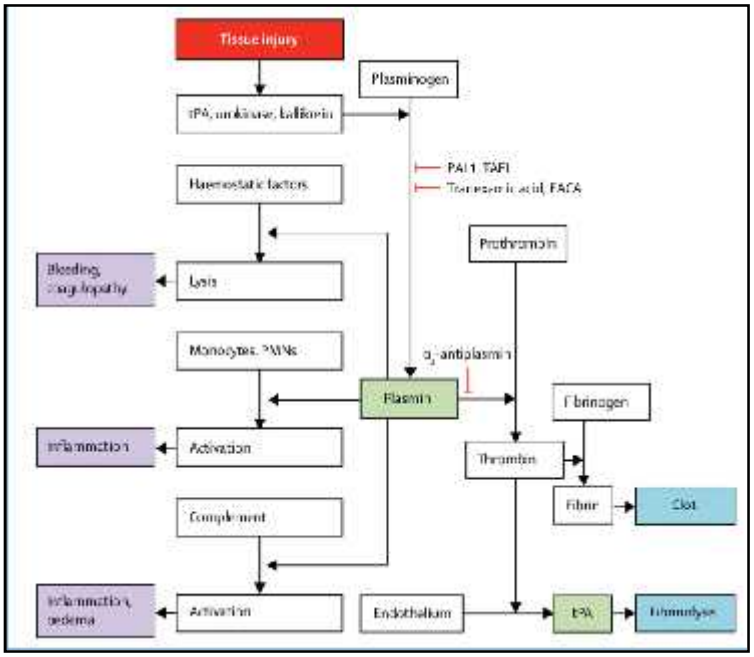
Inflammatory response takes place at the placental bed after delivery of placenta promoting local coagulation. This response allows prevention of haemorrhage at the placental site whereas in other sites these thrombi are less likely to persist as a result of increased fibrinolysis. Such a haemostatic mechanism employed at placental separation involves the muscle sheaths to contract around the

spiralledarteries, thus a platelet plug is formed, mechanical occlusion of arterioles is caused by retraction of uterus facilitating platelet plug formation, activation of both the clotting cascade and fibrinolysis. Fibrinolysis is a key component of the haemostatic processes that is implicated in pathogenesis of coagulopathy after both tissue damage and trauma. [12]

Proposed pathways of the changes of fibrinolysis in post-partum hemorrhage [13]



Tranexamic acid and its relationship with tissue injury, fibrinolysis, and inflammation [18]



The enzyme 'tissue plasminogen' activator (tPA) transforms circulating plasminogen into serine protease plasmin, thus inducing breakdown into fibrin degradation products (FDP).Hypo perfusion, hypoxia, and up-regulation of tPA have been postulated to contribute to maintain the equilibrium of haemostasis against hyper fibrinolysis and subsequent coagulopathy. Fibrinolysis is controlled through changes in blood markers such as D-dimer, FDPs, Plasminogen inhibitor-1 activator(PIA).[14]Abilityin predicting PPH from antepartum and intrapartum risks is unreliable, early detection and treatment of PPHmust be the priority of efforts to minimize adverse outcomes.

Active management of third stage of labor

Based on Wolrd Health Organisation (WHO) Recommendations for AMTSL, 2012, for all births, the use of uterotonics in PPH prevention during the third stage of labor is recommended. Oxytocin is approved uterotonic drug used to prevent PPH. Controlled cord traction for vaginal births is recommended. Evaluation of the postpartum uterine tonus is recommended to detect uterine atony early.[15]

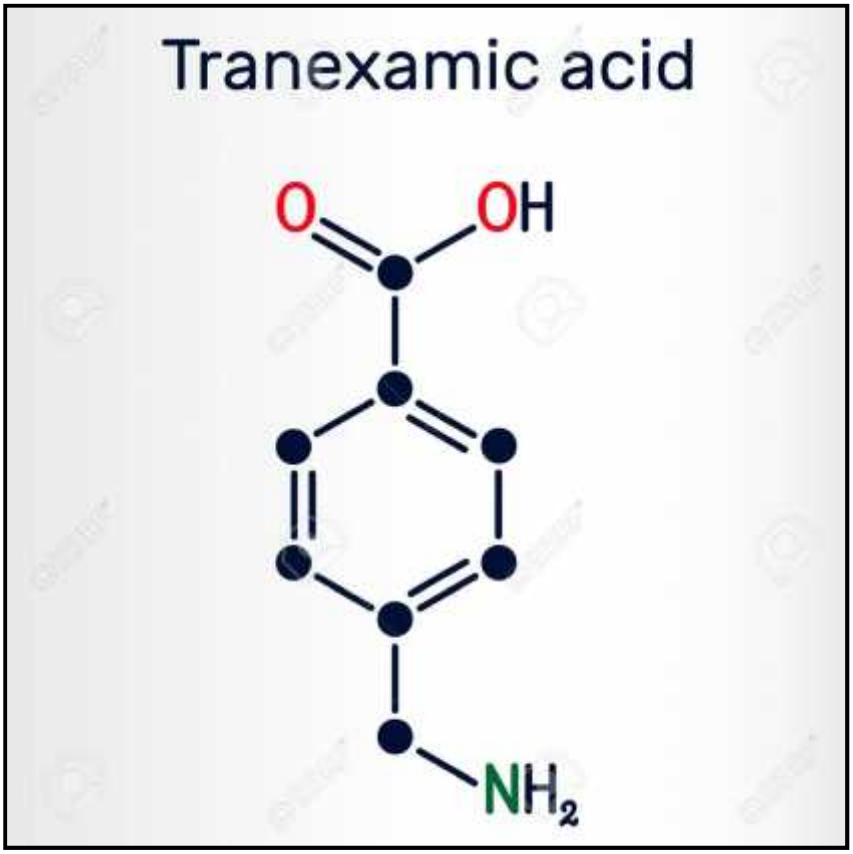
Assessment of blood loss

Calibrated obstetric drape- Brasss V Drape

This comes in sterile packing and fold out to a 1 × 1 metre sterile areafor a woman to give birth. At the bottom of the sterile area is acalibrated pouch that holdsmore than 2500 ml of fluid, allowing for accurate measurement of postpartumblood loss.[44]

Tranexamic Acid

Chemical formulation - Tranexamic acid is a trans-stereoisomer of 4-(aminomethyl)cyclohexane-carboxylic acid) and has a molecular weight of 157[37]



Chemical structure depiction.

Mechanism of action

Tranexamic acid belongs to Food and Drug Administration (FDA) group B drug.

Tranexamic acid is a synthetic derivative of the amino acid lysine and binds the 5 lysine binding sites on plasminogen. This inhibits plasmin formation and displaces plasminogen from the fibrin surface. It may also directly inhibit plasmin and partially inhibit fibrinogenolysis at higher concentrations. Tranexamic acid is also thought to exert an anti-inflammatory effect by inhibiting plasmin-mediated activation of complement, monocytes, and neutrophils and may improve platelet function in certaincircumstances. [38]

Dosage

The oral dose is 1–1.5 gm , 2–3 times per day.

I.V. dosage is typically 0.5–1 gm by slow injection 3 times per day.[1]

As per the WHO 2017 TXA updated recommendation on use of TXA in PPH, TXA is indicated in all cases of PPH, regardless of whether the bleeding is due to genital tract trauma or other causes.

TXA is to be administered within 3 hours and as early as possible after onset of PPH. TXA should be avoided more than 3 hours after birth, unless being used for bleeding that restarts within 24 hours of completing the first dose.

A fixed dose of 1 gm in 10 ml (100 mg/ml) I.V. at 1 ml per minute (i.e., administered over 10 minutes). Second dose of 1 gm I.V. if bleeding continues after 30 minutes or if bleeding restarts within 24 hours of completing the first dose[1]

Pharmacokinetics

The substance can be administered orally or intravenously and has an oral bioavailability ranging from 30–50% with a plasma protein binding of 3% .TXA can completely cross the placenta.[41]

Metabolism

Since TXA has a renal clearance of upto 95%,it is best avoided in women severe kidney dysfunction. [42]

Indications

1)Medical indications

Hereditary angioneurotic oedema

Upper gastrointestinal tract bleeding

Reversal of drug induced bleeding

2)Elective surgery

Oral surgery

Cardiac surgery

Orthopaedic surgery

Liver surgery

Neurosurgery

Urological procedures

Obstetric and gynaecological[39] - Oral tranexamic acid is used in as an effective treatment ofmenorrhagia.Intravenous tranexamic acid is used in treatment of acute PPH.

Side effects

Nausea, vomiting, diarrhoea – commonest side effect, occurs in 10% of cases

Giddiness and hypotension – if given by sudden rapid iv occurs in 1- 10% of cases.[40]

Defective colour vision – if used for long time

Thromboembolism

Drug allergy – rare

Contraindications

- Known allergy to TXA
- Intracranial bleeding
- Known defective colour vision
- History of venous or arterial thromboembolism
- Active thromboembolic disease.[43]

Cautions

TXA is a pregnancy category B drug. No harm or small risk has been noted in animal studies, but no risk seen in human studies.

TXA is not well studied in the renally impaired. It is 95% excreted in urine, so renal dosing is recommended and judicious administration in patients with severe renal impairment.

No adjustments required in the hepatic impaired patient.

Drug Interactions

Chlorpromazine increases cerebral vasospasm when combined with Tranexamic Acid, so it should not be combined.

Factor IX when given along with Tranexamic Acid will lead to increased thrombosis risk.[18]

Effects 0F PPH

PPH life-threatening complication of delivery of vaginal and caesarean sections.[16]

Risks associated with uncontrolled hemorrhage	**Risk associated with fluid resuscitation**	**Risk associated with blood transfusion**	**Risk associated with surgical intervention**

- uncontrolled hemorrhage
- fluid resuscitation
- exposure to blood products

Effects of PPH			
[illegible]	Pulmonary and [illegible]	[illegible]	Intubation and complications
Postpartum hypopituitarism	Dilutional coagulopathy	Anaphylactic reactions	Persistent bleeding
Death - secondary to hypovolemic shock		Transfusion-related acute lung injury	Infection
		Acute immune hemolytic reaction	Deep vein thrombosis Pulmonary embolism
		Delayed hemolytic reaction	
		Infection	
		Metabolic reactions hypothermia hyperkalemia citrate toxicity	

- surgical intervention

Management of PPH

A) <u>Medical management</u> [10]

UTEROTONICS

i. Oxytocin – 10 units i.m. / i.v. followed by 20 units i.v. infusion in 500 ml ringer lactate / normal saline
ii. Methylergometrine – 0.2 mg i.m. / i.v. repeated for every 15 minutes to a maximum of 5 doses
iii. 15 methyl PG F2α - 250 microgram (µgm) i.m. repeated every 15 minutes to a maximum of 8 doses
iv. Misoprostol – 400 - 1000 microgram by vaginal, oral, rectal route
v. Recombinant factor VIIa – 60 – 120 microgram/ kg i.v. route
vi. TXA – 1 gram intravenous every 8th hourly

B) SURGICAL MANAGEMENT [34]

i. Bimanual compression

ii. Uterine balloon tamponade

iii. Compression sutures

iv. Arterial ligation

v. Aortic clamping

vi. Total / subtotal hysterectomy

C) INTERVENTIONAL RADIOLOGY- Can be considered on stable patient with continued bleeding pelvic arterial embolization is a minimally invasive life-saving therapy that preserves patient quality of life and speeds recovery for women with PPH.[35]

In a meta-analysis of randomized controlled trials (RCTs) performed by Loic Sentilhes and Catherine Deneux-Tharaux in the year 2016 which included 3285 women with cesarean section or vaginal delivery ,to study the effect of prophylactic one dose of one gram of TXA against placebo or nil intervention after vaginal or caesarean delivery, in addition to prophylactic uterotonics, blood loss more than 400 or 500 mL and more than 1000 mL was significantly less in women receiving the TXA than placebo or not receiving any intervention. Additional medical procedures, needfor blood transfusion were less commonly seen in women who received TXA versus placebo or did not undergo any intervention. Mild gastrointestinal adverse effects were common among women receiving TXA, but the impact of TXA was unknown on maternal deaths, extreme morbidity & thromboembolic events. [7]

In a " randomized, double-blind , placebo-controlled study conducted by the WOMAN Research Collaborators between 2010 and 2016, aimed at assessing the impact of early administration of TXA on mortality and hysterectomy in women with PPH", which recruited women with a clinical diagnosis of PPH after a caesarean section or vaginal birth . A total of 20,060 women were registered & randomly assigned to receive "either 1 gram intravenous TXA or equivalent placebo" alongside with the center standard care. Bleeding causing death in women given tranexamic acid was significantly reduced particularly if treated within 3 hours of birth. Necessity for hysterectomy and adverse effects, however, did not substantively differ between 2 groups. "This implies that TXA prevents mortality due to bleeding in women with PPH without adverse effects and is most effective if administered as soon as bleeding has started" [(5)]

In "double-blind RCT" by Sentilhes et al in 2015 to test impact of 1 gram tranexamic acid post vaginal delivery on the incidence of PPH in term , singleton women for "a planned vaginal delivery with live fetus", In conjunct to "prophylactic oxytocin, 1 gm IV tranexamic acid or placebo was administered within 2 minutes of delivery of baby". A total of 4079 women were registered and consented, and 3891 delivered vaginally.Incidence of primary outcome which was incidence of PPH, characterized by blood loss of 500 ml prevailed in the TXA group at 8.1 percent and in placebo group at 9.8 percent. In TXA acid group need for additional uterotonics was lower as compared to the placebo group. While nausea or vomiting were more seen in the TXA population, no major adverse events like thrombotic events were observed. Thus, it follows that TXA was linked to a reduced risks of PPH than placebo without increasing risk of serious adverse effects within 3 months of delivery.[(9)]

In 2001, an RCT was published by Yangand colleagues comparing four classes. One group was given a "single dose of 1 gram TXA by intravenous infusion"; a single dose of 0.5 gram TXA was given to another group.The third group obtained a "single dose of 0.5 gm amino methyl benzoic acid intravenously, and the fourth group was control group". However this study had drawbackslike lack of placebo and blinding. This study, identified a “lower incidence in PPH in women receiving the larger TXA dose than those of control group". (4)

In a "prospective double-blinded, placebo-controlled study performed by Gundorkuk and colleagues in 2010", 439 patients were enrolled in a "double-blinded RCT" with vaginal deliveries. Women belonging to “intervention group obtained a single 1 gram TXA I.V. dose at the anterior shoulder delivery, and those in the control group obtained placebo". The "primary result was mean calculated blood loss during third and fourth stage of labour". In the "TXA group,the mean calculated blood loss was significantly lower than the placebo group". In addition,the overall blood loss of1000 ml among women who received placebo (2.3 percent) was higher than among women who received TXA (0.5 percent) but the difference was not statistically significant". In the placebo group (8.7 per cent) significantly more women than the TXA group (2.7 per cent) utilized additional uterotonics. However, no significant difference was reported for need of blood transfusion. Pre- delivery levels of hemoglobin & hematocrit where same between groups, however post delivery, the levels of hemoglobin and hematocrit were greater in the TXA than in placebo group.. No cases of thrombosis occurred in women obtaining TXA. These finding of a single-center study indicate that TXA is a promising medication for prevention of PPH, and probably for reducing maternal morbidity. Slight transient adverse effects, including

gastrointestinal tract symptomsincluding nausea and vomiting, can be associated with use of TXA.[17]

In "2010 CRASH-2 trial , multi-center randomized, double-blinded, controlled trial where patients either received TXA or a placebo in adult trauma patients with significant hemorrhage with systolic blood pressure (BP) < 90 mmHg, heart rate>/=110 beats per minute, and within 8 hours of injury. They found TXA to improve survival if administered in three hours from time of injury in patient population with significant hemorrhage".This study showed a statistically significant reduction in deaths worldwide without thromboembolic events having increased in the TXA group. In trauma patients who obtained TXA there was a statisticallysignificant decrease in risk coronary heart disease. It also suggested that TXA administration might cause AKI due to cortical ischemia mediated by thrombosis.[18]

"MATTERs trial in 2011 revealed TXA decreased overall mortality, notably those requiring massive transfusion protocol. This is the only trial that has shown increase rate of thrombosis"[19]

In 2017 a report by Ingrid Pabinger et al. to review TXA's hypersensitivity during pregnancy, folllowing adverse events were noted

- Disturbance of color vision
- Massive bleeding in upper urinary tract
- Acute venous or arterial thrombosis
- Severe renal impairment
- Intracerebral bleed
- Disseminated intravascular coagulation without severe hemorrhage[20]

According to a Cochrane analysis in the year 2010, "randomized, controlled studies administration of 0.5 gram and 1gram respectively, of TXA reduced both blood loss and transfusion needs after vaginal births and cesarean sections".A systematic review which included "1760births also found that the administration of TXA as compared with placebo resulted in a significant reduction of blood loss and the frequency of allogenic transfusion". [(8)]

The European Anaesthesiologic Society Recommends that TXA be prescribed forhemorrhage peripartum and postpartum to minimize the amount of blood loss, duration of bleeding and the need for blood allogeneic products.[(21)]

In a meta-analysis performed by Asim Alam and Stephen Choi in the year 2015 which included Eighteen trials which concluded 3846 subjects, with 1935 patients receiving TXA. Prophylactic TXA administration was associated with a decrease in incidence of PPH with reduction in mean blood loss and a reduction in blood transfusions along with a reduction in useof uterotonics. It turned out there was no increased risk of thromboembolism, and no significant difference in length of hospital stay after the use of TXA. [(22)]

The "Guideline Development Group" (GDG) was convened in August 2017 to study& evaluate the cost-effectiveness, validity, and viability of PPH therapy with TXA. The GDG endorses intravenous treatment with TXA at a fixed dose that is 1 gram at 1 ml / minute with2nd dose of 1 gram intravenously if bleeding occurs after 30 minutes, or if bleeding stops and starts within 24 h after 1st dose is done. In context of this guideline, the term "clinically diagnosed postpartum haemorrhage refers to a clinically measured blood loss of > 500 ml after vaginal birth or 1000 mlpost caesarean section , or any blood loss sufficient to impair hemodynamic stability". The GDG noted that in cases of PPH, tranexamic acid should be

administered, irrespective as to whether bleeding is believed to be caused by injury to the genital tract or for other causes likeuterine atony. This revised guideline is clearer than the previous 2012 guidelines, which recommended that TXA should only be used for PPH care if oxytocin and other uterotonics do not stop bleeding, or if it is suspected that the bleeding might have been due to trauma in genital tract. [23]

In a study conducted by AP Xia et al in 2020 that "compared the clinical effectiveness of TXA administration on vaginal deliveries with newly published papers using electronic databases". The "randomized controlled trials were divided between TXA and control groups.The related research involved four trials of 4579 patients. TXA treated patients reported a decrease in overall blood loss and reduced postoperative blood loss with a P<.00001 which was statistically significant. However, there was no significant difference in the amount of transfusions required. Two studies involving 4164 patients recorded nausea or vomiting, which was higher in TXA treatment group than control group". They examined 4 studies involving dizziness, 2 studies with reports of photopsia between patients treated with TXA or control group. However, occurrence of dizziness or photopsia were not statistically significant.[24]

A Cochrane systematic review evaluating TXA for preventing post-partum haemorrhage was recently published. After the analysis of 12 RCTs involving 3,285 women, the authors concluded that TXA decreases postpartum blood loss and prevents PPH and blood transfusion requirements. [25]

In the EXADELI trial, which was an "open-labelled,randomized controlled, multicentered study. Women with PPH > 800 ml following vaginal delivery were randomly allocated to receive TXA or nil intervention. Packed red blood cells (PRBCs) and colloids could be used in both groups as allowed by French guidelines.

The use of additional procoagulant therapies was only approved in cases involving intractable bleeding. The primary goal was to determine the effectiveness of TXA in reducing blood loss in women with PPH and the secondary goals were the impact of TXA on duration of PPH, anaemia, transfusion, and the need for invasive procedures. A total of 144 women completed the protocol altogether. Blood loss between enrolment and 6 hours later was significantly lower in the TA group than in the control group compared to controls witha P value of 0.041. Bleeding period in the TXA group was shorter, and progression to extreme PPH and PRBC transfusion was significantly lower than in controls witha P< 0.03. Invasive procedures were carried out in the TXA group of four women and in seven controls and was not statistically significant. PPH stopped in 93 per cent of women in the TXA group after only uterotonics and PRBC transfusion versus 79 per cent of controls"[(26)]

MATERIALS AND METHODS

a) Source of Data

Term pregnant women admitted to labour room and undergo vaginal delivery at tertiary care hospital

b) Method of collection of data

i) Studydesign: Randomized controlled trial

ii) Study setting: KLE's DR. Prabhakar Kore Charitable Hospital, Belagavi

iii) Duration of data collection: 1 year

iv) Study Period: January 2019 – December 2019

v) Study Population: Term pregnant women admitted to the labour room and undergo vaginal delivery at KLE's DR. "Prabhakar Kore Charitable Hospital", Belagavi

vi) Sample size:

Oxytocin was administered as a routine management of thirdstageoflabour to both the groups.

P 1 - taken by assuming, oxytocin and tranexamic acid will reduce 50 % of

PPH

Therefore P 1 = 50

P 2 - taken by assuming oxytocin and placebo will reduce 30 % of PPH

Therefore P 2 = 30

P 1 = 50

P 2 = 30

P =p1+p2 /2

P=50+30/2

P=40

q= 100-p

q= 60

Calculation of sample size

n= 2 (z alpha+ z beta) ^{2} (pq)/ (p1-p2) ^{2}

Z alpha= 1.96 at 5 % alpha error

Z beta = 0.842 at 20 % beta error

p1-p2 =20

n= 2(7.84) x2400/20 X20 =94

n =100 in each group

vii)ANALYSIS-

To compare the outcome by the quantity of blood loss in each group.

Data analysis was done using R i386.3.6.3. statistical software. Continuous data represented in the form of mean ± SD and the categorical variable was represented by the frequency table. Association between categorical variable was studied using chi-square test. Between group comparison was done using t-test/Mann Whitney U-test. Within group comparison was done using Wilcoxon sign rank test. P-value<0.05 was considered as statistically significant

viii) Sampling procedure- Computer generated randomization chart used.

ix)Randomization- Women were randomized into 2 groups based on computer generated randomization chart.

Selection Criteria:

Inclusion criteria:

- Term pregnancy
- Planned vaginal delivery
- Singleton pregnancy

Exclusion criteria:

- Known side effects to drugs - History of thrombosis - venous-deep vein thrombosis, angina pectoris, myocardial infarction,stroke,epilepsy, seizure disorder
- Known cardiovascular, renal or liver disorders
- Autoimmune disease
- Sickle cell disease
- Severe haemorrhagic disease
- Placental Abnormality-placenta accreta / placenta previa
- Severe Pre-eclampsia(PE) , Eclampsia and Haemolysis, Elevated Liver Enzymes and Low Platelet(HELLP) syndrome
- Intrauterine fetal demise (IUFD)
- Administration of Low Molecular Weight Heparin or antiplatelet agents
- Previous caesarean sections

Methodology:

Participants were enrolled as per inclusion criterion after providing written informed consent. The eligible study participants were randomized by computer based randomizationchart into2 groups. Both groups received 10 units prophylactic oxytocin as intramuscular injection as an active management of third stage labor. In one group intervention was 1 gram TXA intravenously slowly over 30-60 seconds in 2 minutes after delivery of the baby. In the other group intervention was administration of 10 milliliters(ml) of normal saline slowly over 30 to 60 seconds in the 2 minutes after delivery of baby. Graduated collector bag,brasss V drape bag was placed under the buttocks of woman and tied around the waist. The funnel portion is the calibrated portion of the bag by which the quantity of blood loss was measured in milliliters. The

bag was kept in place until the obstetrician decided that the bleeding was stopped. The quantity of blood loss was measured at endof 30 minutes and at the end 2 hours from time of delivery of baby.

Hemodynamic parameters which include pulse rate and blood pressure was checked in both the groups every 15 minutes for the first hour and then at the end of second hour.

Patients belonging to both groups were asked for symptoms of immediate minor adverse effects of TXA which included nausea, vomiting and dizziness in the labour room. Participants of both the groups were followed up till date of discharge to know if they required blood transfusion or additional surgical intervention to control the blood loss which include peripartum hysterectomy and arterial embolization.

On the post natal day 2, laboratory parameters which included Haemoglobin (Hb)& Packed cell volume(PCV), were checked. The mean change in Hb and PCV was calculated by the difference between the values measured before delivery & on postnatal day 2.

Participants of both the groups were followed up in the post natal period up to 3 months. In the follow up, participants were asked for symptoms of major adverse effects of drug like breathlessness, chest pain, seizure episodes. If symptoms were presentthey were evaluated for following conditions - deep vein thrombosis, pulmonary embolism diagnosis confirmed by radiological examination,myocardial infarction – diagnosis confirmed by ECGSeizure episodes, renal failure needing dialysis.

RESULTS

In this study a total of 350 participants were screened for the study. A total of 104 participants were excluded as per the exclusion criteria of the study.

A total of 246 participants were enrolled and randomized in this study, of which 36 participants required caesarean section. Here totally 210 subjects were considered for the study consisting of 105 and 105 subjects in TXA and Placebo groups respectively.

CONSORT DIAGRAM

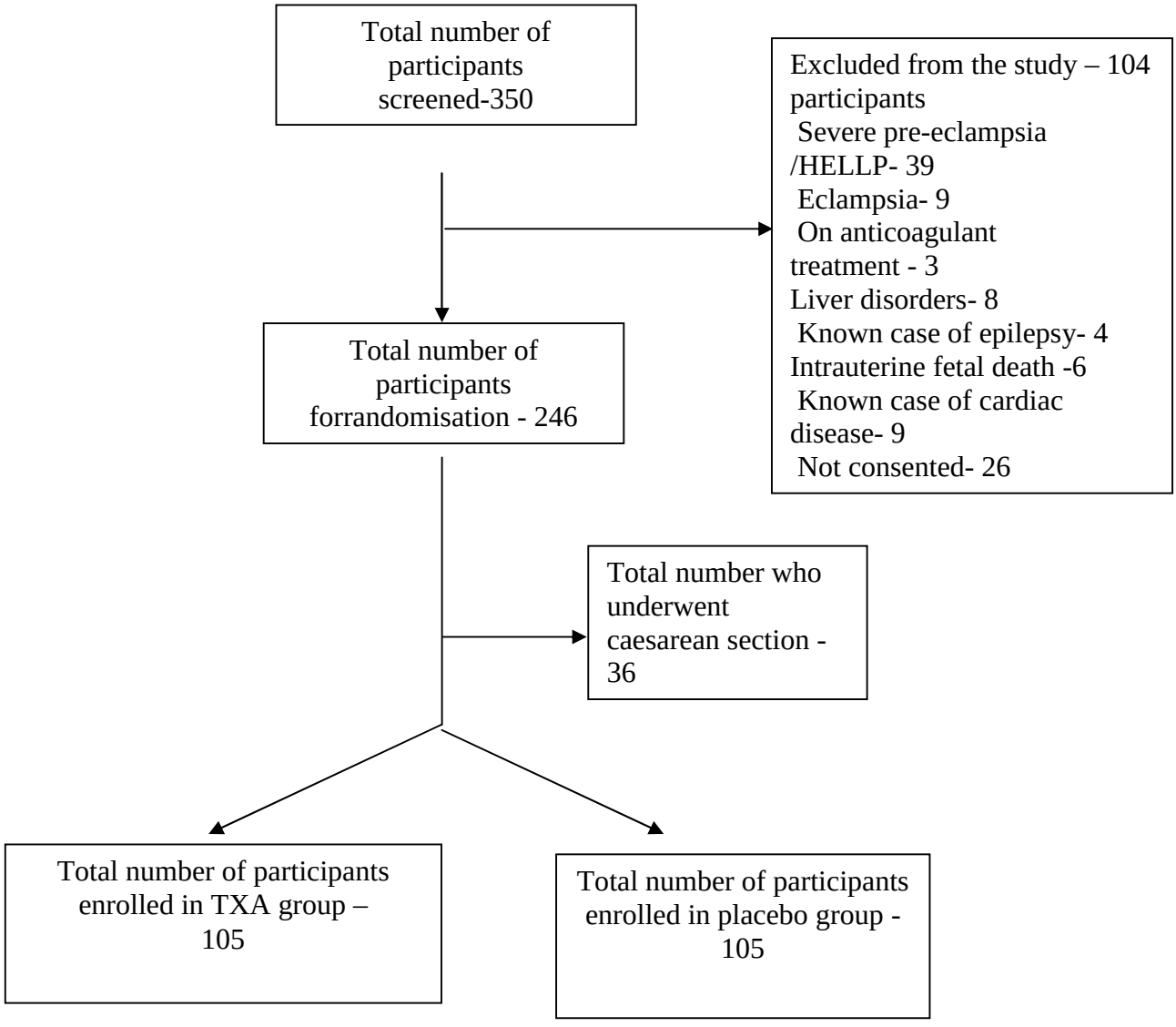


Table -1

Distribution according to maternal age

Maternal age	TXA group	Placebo group	P value
18-22 years	49 (46.67%)	42 (40%)	0.3218[F]
23- 27 years	44 (41.9%)	43 (40.95%)	
28-32 years	11 (10.48%)	19 (18.1%)	
33- 37 years	1 (0.95%)	1 (0.95%)	
Mean age (in years)	24.11 ± 4.1	23.53 ± 3.06	0.1008[M]

[F] indicates fisher's exact test ;[M] indicates Mann-Whitney U-test

Here totally 210 subjects of mean age 23.43±3.26(in years) varies from 18 to 37 years were considered for the study consisting of 105 and 105 subjects in TXAgroup and Placebo groups respectively. It was observed that majority of the subjects in TXA and placebo group belonged to the age group 18-22 years and 23-27 years respectively whereas the least number of subjects were of the age group 33-37 years. Descriptive statistics based on age of each group is shown in table 1 and graph 1.

Graph 1

Distribution according to maternal age

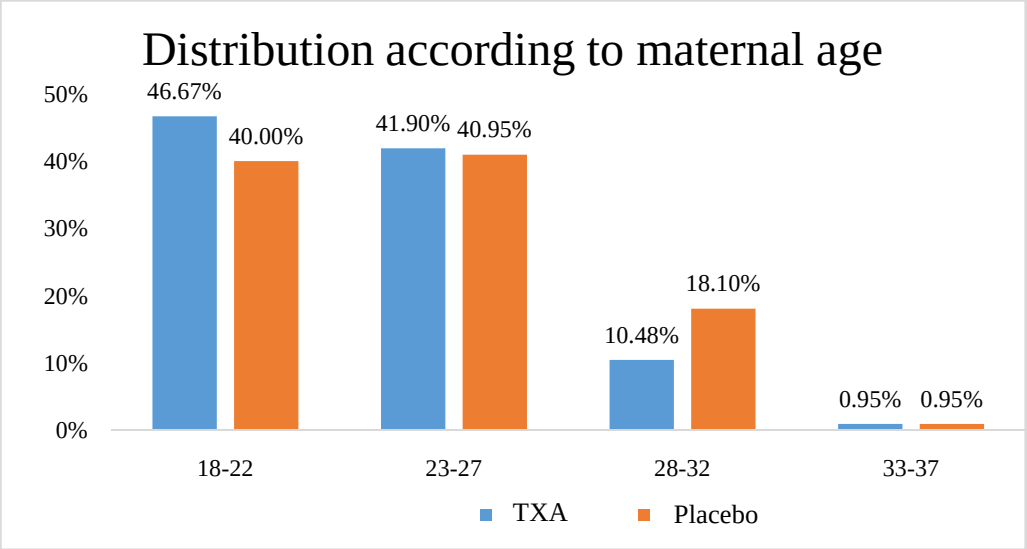


Table – 2

Distribution based on gravidity

Gravidity	TXA group	Placebo group	P value
Primigravida	47(46.6%)	46(42.06%)	0.6537 [C]
Multigravida	58(55.34%)	59(56.07%)	
Total	105	105	

[C] indicates Chi-square test

In this study, 46.6 % of participants and 42.06 % of the participants were primigravida's in the TXA group and placebo group respectively whereas 55.34% and 56.07 % of the participants were multigravida in the TXA group and placebo group respectively, with a P value of 0.6537.

Descriptive analysis of distribution of participants based on gravidity is depicted in table 2 and graph -2

Graph -2

Distribution based on gravidity

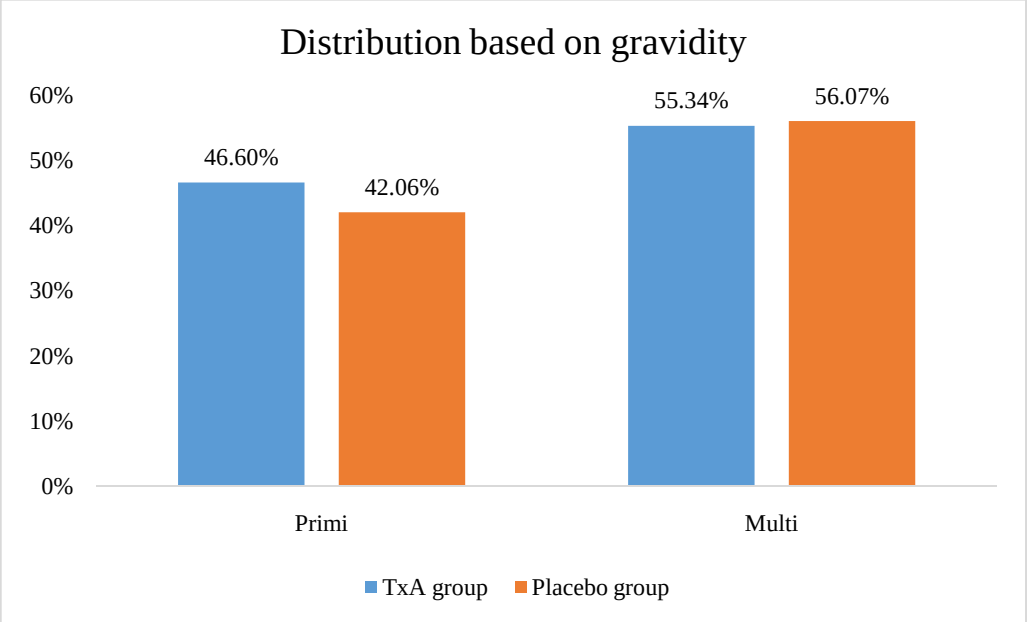


Table -3

Distribution based on gravida score

Gravida	TXA group	Placebo group	P value
1st Gravida	45 (42.86%)	46 (43.81%)	1
2nd Gravida	40 (38.1%)	39 (37.14 %)	
3rd Gravida	15(14.29%)	15 (14.29%)	
4th Gravida	3(2.86 %)	4 (3.81%)	
5th Gravida	2 (1.9%)	1(0.95%)	
Total	105	105	

In this study, majority of the participants belonged to 1st gravida with 42. 86% in TXA group and 43.81% in the placebo group. The least number of participants belonged to 5th gravida with 1.9 % in the TXA group and 0.95% in the placebo group, with a P value of 1.

Descriptive analysis based on gravida score of the participants depicted in table 3 and graph 3.

Graph - 3

Distribution based on gravida score

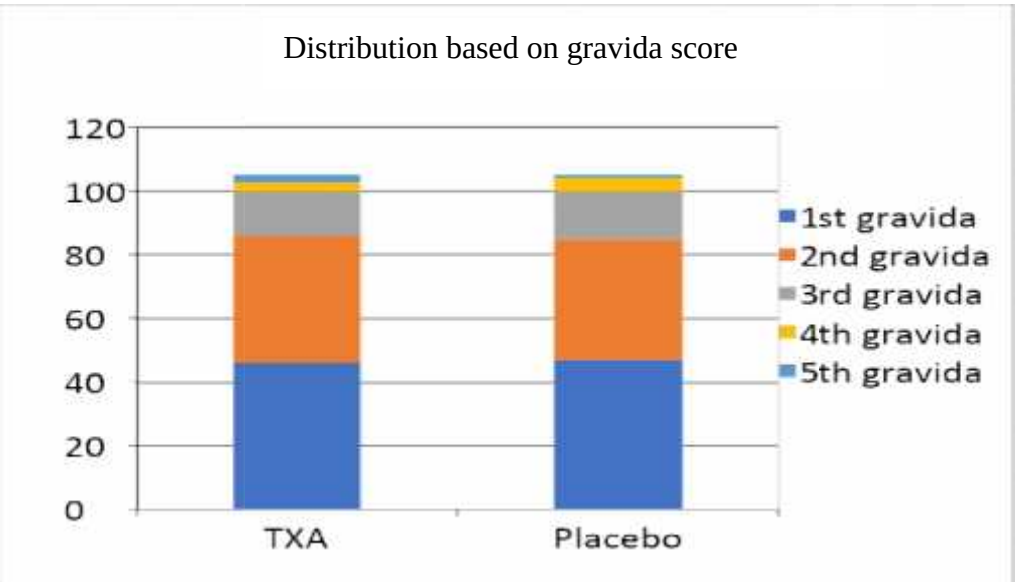


Table -4

Distribution based on body mass index(BMI)

BMI(kg/m^2)	TXA group	Placebo group	P value
< 18.5 (underweight)	4 (3.81 %)	3 (2.86%)	
18.5 – 24.9 (normal weight)	63 (60 %)	65 (61.9%)	
25-29.9 (pre obesity)	26 (24.76%)	28 (26.67%)	
30-34.99(class 1 obesity)	12 (11.43%)	9 (8.57%)	0.95
35-39.9(class II obesity)	0(0)	0 (0)	
Above 40 (Class III obesity)	0 (0)	0 (0)	
TOTAL	105	105	

In the present study, majority of the participants had a BMI within normal range, with 60 % participants in TXA group and 61.9 % in the placebo group, with a P value of 0.95.

Descriptive analysis of distribution of participants based on BMI in the 2 groups shown in table 4 and graph 4

Graph 4

Distribution based on body mass index(BMI)

Distribution based on body mass index (BMI)

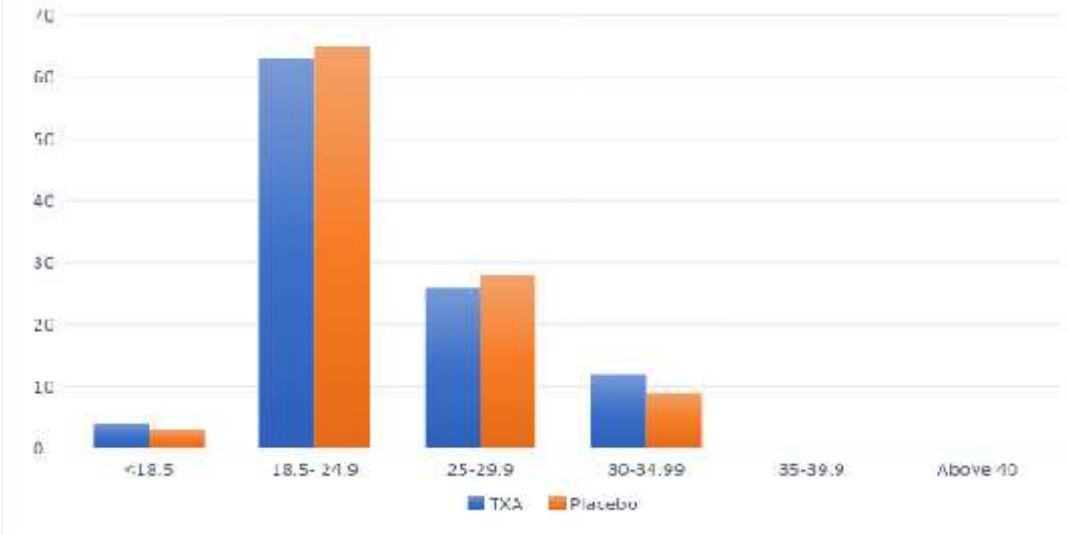


Table- 5

Incidence of postpartum haemorrhage

	TXA group	Placebo group	P value
Incidence of PPH	5(4.85%)	12(11.21 %)	0.0912 [P]

p - proportion test

In this study, of the 210 participants, 17 women had postpartum haemorrhage. Itwas observed that incidence of PPH in TXA group and Placebo group was 4.85% and 11.21% respectively with a P value of 0.0912.

Analysis of incidence of postpartum haemorrhage shown in table -5 and graph 5.

Graph -5

Incidence of postpartum haemorrhage

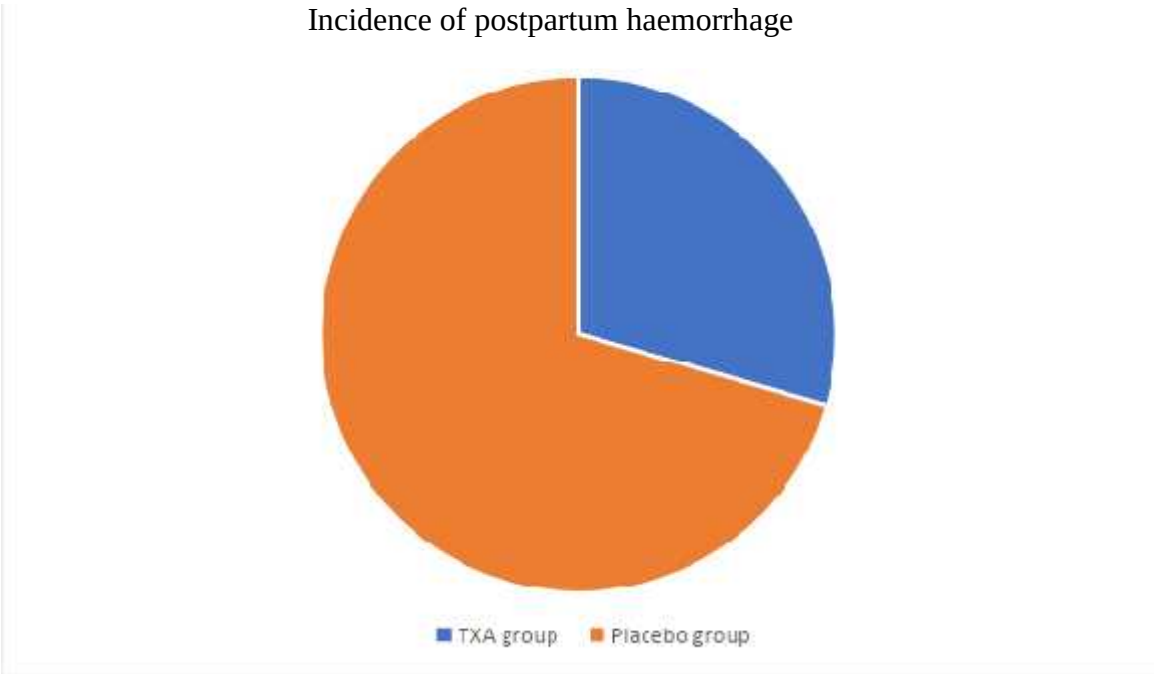


Table -6

Incidence of atonic and traumatic postpartum haemorrhage in TXA group and Placebo group.

Incidence of PPH	TXA Group	Placebo group	P-value
Atonic PPH	3 (2.86%)	8 (7.62%)	0.21
Traumatic PPH	2 (1.9%)	3 (2.86%)	0.72
Atonic + traumatic	0 (0%)	1 (0.95%)	1

In the present study, the incidence of atonic PPH was 2.86 % in TXA group and 7.62 % in placebo group with a P value of 0.21. Incidence of traumatic PPH was 1.9% in TXA group and 2.86 % in placebo group with a P value of 0.72. There was no occurrence of traumatic with atonic PPH together in the TXA group, whereas0.95 % incidence was present in the placebo group.

Analysis of atonic and traumatic postpartum haemorrhage in 2 groups is shown in table 6 and graph 6

Graph -6

Incidence of atonic and traumatic postpartum hemorrhage in TXA group and Placebo group

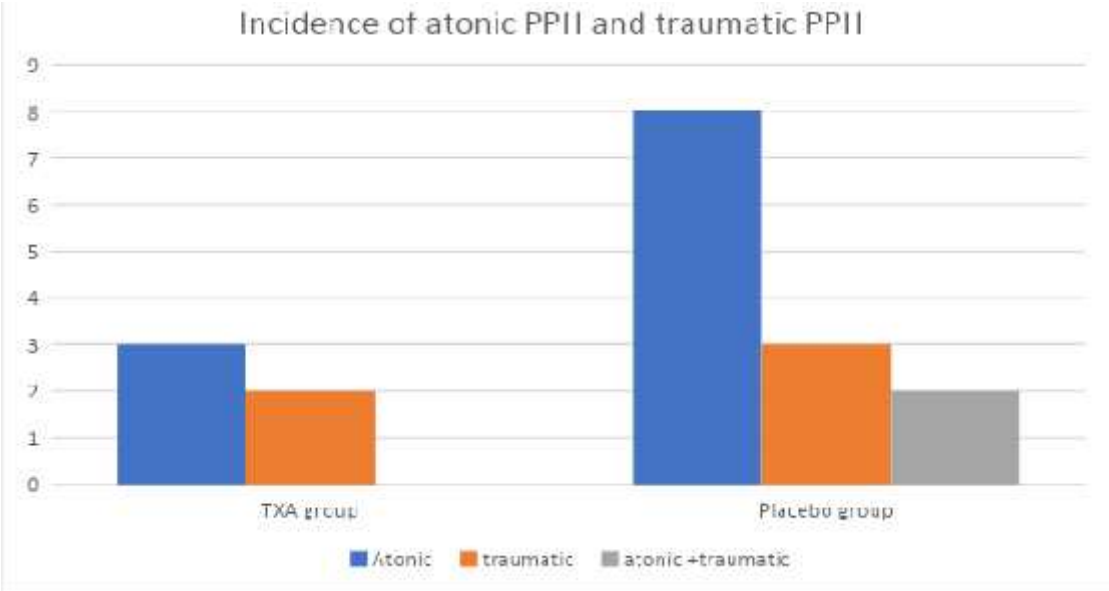


Table -7

Average blood loss in the in TXA group and Placebo group

	TXA group	Placebo group	P value between the groups
Average blood loss	250.10 ±133.54	334.2 ± 141.78	<0.0001[M]

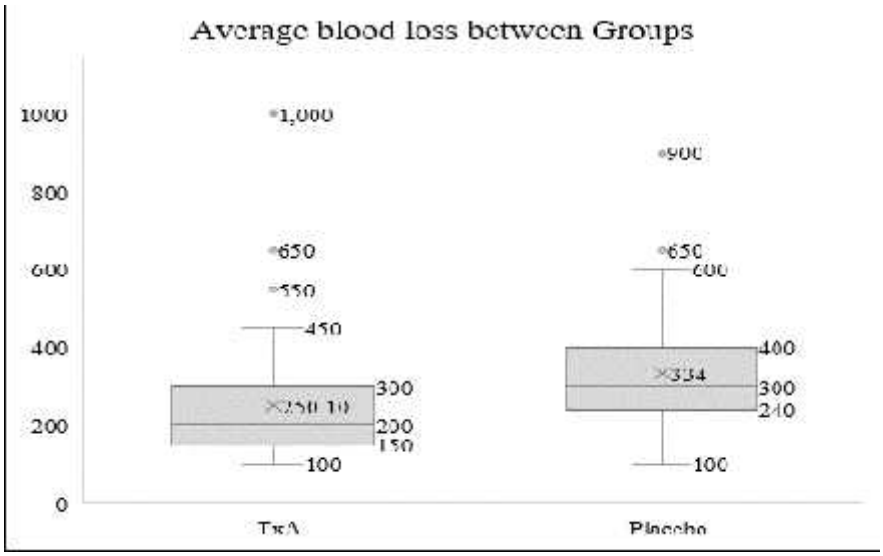
[M] *indicates Mann-Whitney U-test*

In the present study, the mean average blood loss was 250.10 ±133.54ml in the TXA group as compared to 334.2 ± 141.78ml in the placebo group with a P value of <0.0001.

Average blood loss in the TXA group and placebo group is shown in table 7 and graph 7.

Graph- 7

Average blood loss in the TXA group and Placebo group



Median loss was 200ml in TXA group which was less as compared with the Placebo group. 50% of participant had a blood loss between 150-300ml inthe TXA group and the same in placebo group was 240-400ml.

Secondary objectives

Table- 8

Analysis of clinical parameters which include need for postpartum transfusion, arterial embolization and emergency hysterectomy

Parameters	TXA group	Placebo group	P value
Postpartum transfusion	4 (3.88%)	10 (9.35%)	0.1127
Arterial embolization	0	0	0
Emergency hysterectomy	0	0	0

In this study the secondary clinical objective was analysed, it was found that 3.88 % and 93.5 % of the participants in the TXA group and placebo group required blood transfusion respectively, as depicted in table 8and graph 8. No participants of this study required arterial embolization or emergency hysterectomy.

Graph- 8

Analysis of clinical parameters which include need for postpartum transfusion, arterial embolization and emergency hysterectomy

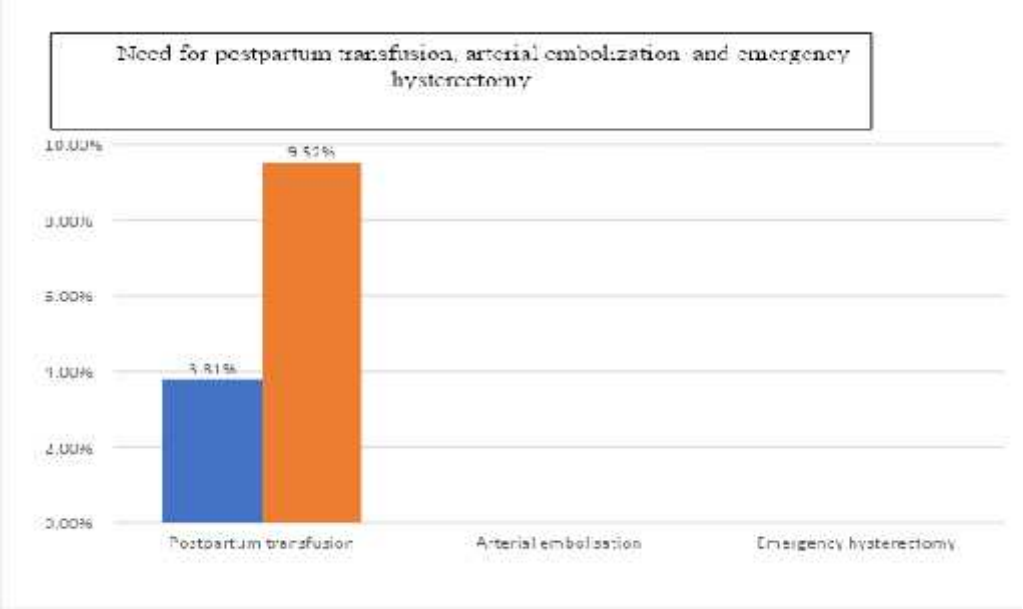


Table -9

Change in lab parameters in the TXA group and placebo group

Change in lab parameters	TXA group	Placebo group	P valuebetween groups
Change in Hemoglobin(Hb)	1.48 ± 1.22	1.82 ± 1.20	0.0066 [T]
Change in Packed cell volume(PCV)	3.51± 3.42	5.05 ± 4.18	0.0015 [T]

[T] indicates T-test

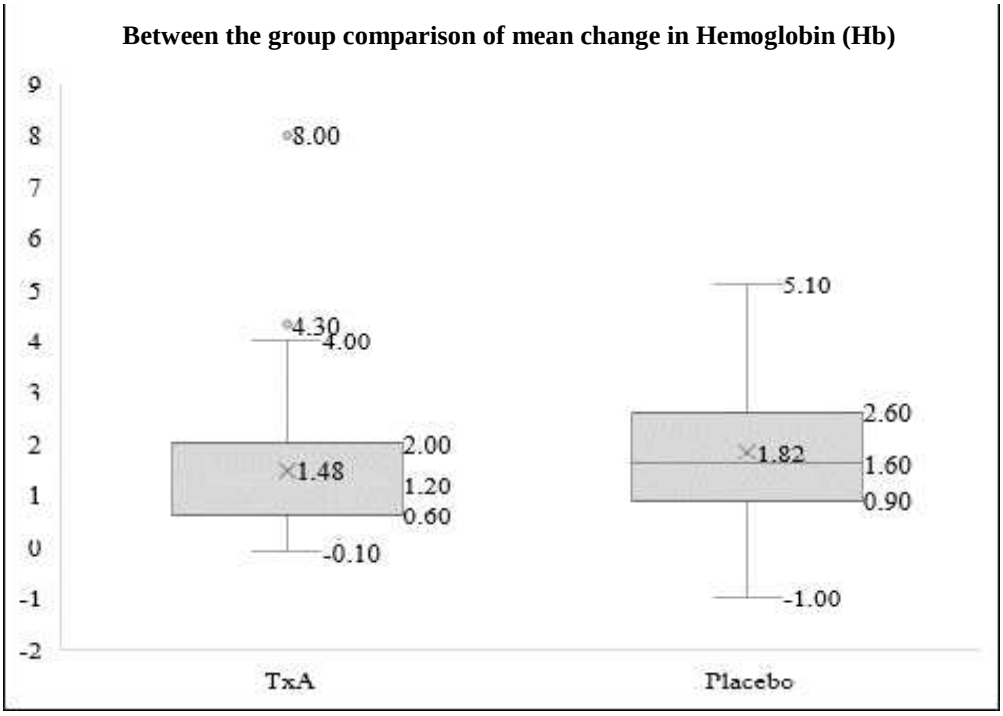
In the present study, change in Hb was 1.48 ± 1.22in the TXA group and inthe 1.82 ± 1.20 placebo group with a P value of 0.0066.

Change in PCV was 3.51± 3.42 in the TXA group and 5.05 ± 4.18 in the placebo group with a P value of 0.0015.

Change in laboratory parameters which include Hb and PCV are depicted in table 9 and graph 9A and 9 B respectively.

Graph-9 A

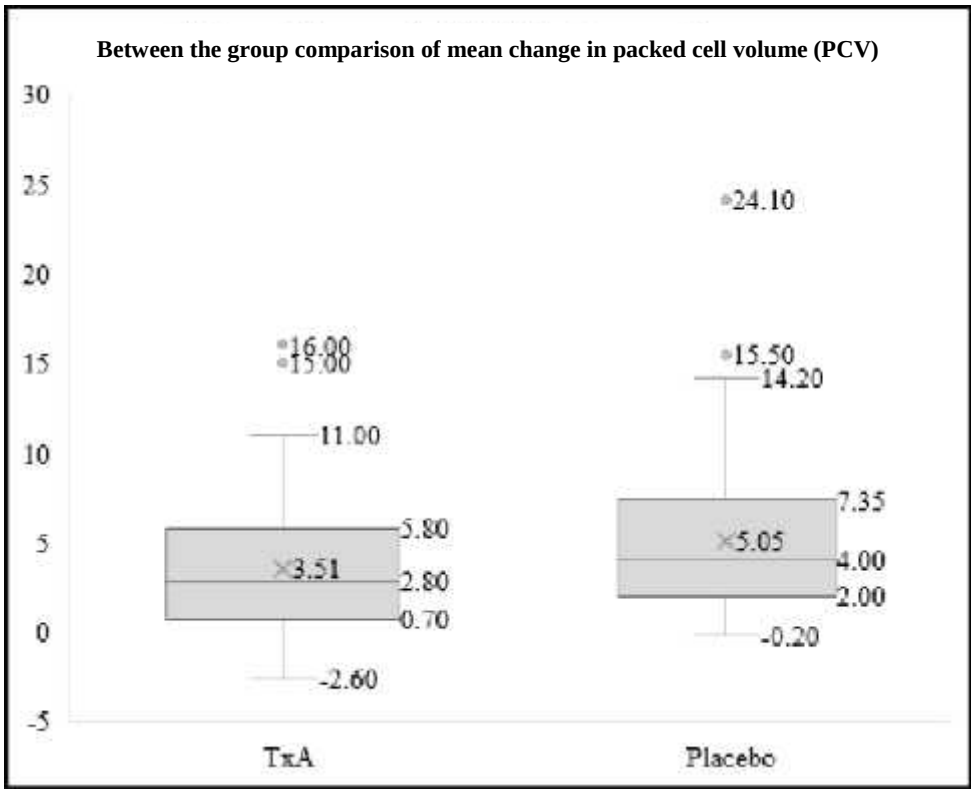
Between the group comparison of mean change in Hemoglobin (Hb)



Median and mean change of Hb in TXA group was less as compared with the Placebo group and was significant. 50% of participant change in Hb was between 0.6-2.00 in TXA group and the same in placebo group was 0.9-2.6.

Graph 9 B

Between the group comparison of mean change in packed cell volume (PCV)



Mean and median change of PCV in TXA group was less as compared with the Placebo group. 50% of participant change in PCV was between -0.7-5.80 in TXA group and the same in placebo group was 2-7.35.

Analysis of vital parameters

Table-10

Mean change in pulse rate between the groups

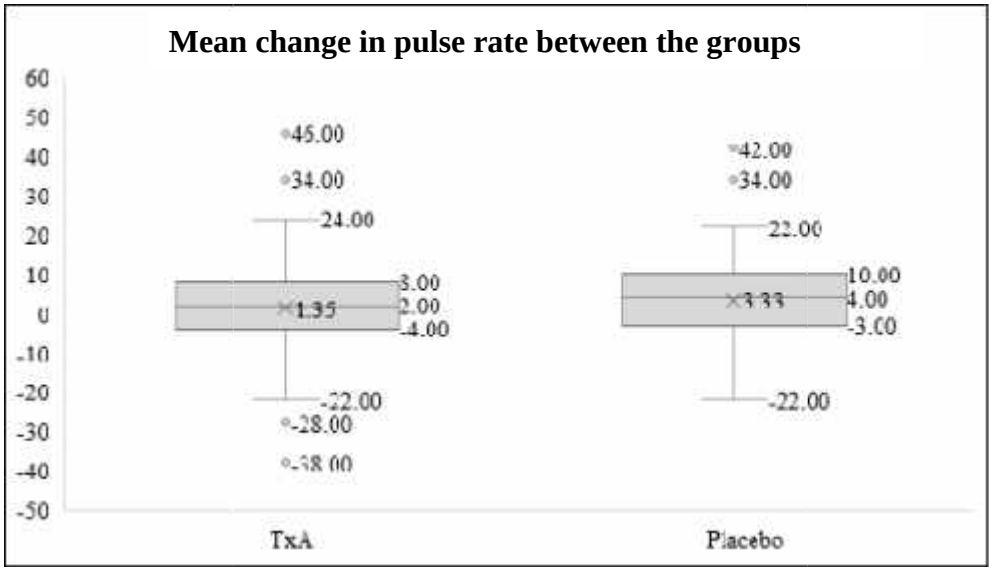
Pulse rate	TXA group	Placebo group	P value between the groups
Pre-intervention	81.64 ± 8.54	79.52 ± 6.48	0.13 [M]
Post-intervention	76.38 ± 9.67	75.41 ± 5.81	0.86 [M]
Change	-1.35 ± 11.44	-3.33 ± 10.79	0.21 [M]
P value (within group)	0.09[W]	0.002 [W]	

[M] indicates Mann-Whitney U-test,[w]indicates Wilcoxon sign test

In the present study, it was concluded that median of pulse rate was not significantly different between 2 groups as well as post intervention. The median of gain in pulse rate was not significantly different between 2 groups. Mean change in pulse rate between the groups is depicted in table 10 and graph 10.

Graph -10

Mean change in pulse rate between the groups



Median and mean change in Pulse rate in TXA group is less as compared with the Placebo group, however they were not significant. 50% of participant change in pulse rate was between -4.0-8.0 in TXA group and the same in placebo group was -3-10.00.

Table- 11

Mean change in Systolic Blood Pressure(SBP)

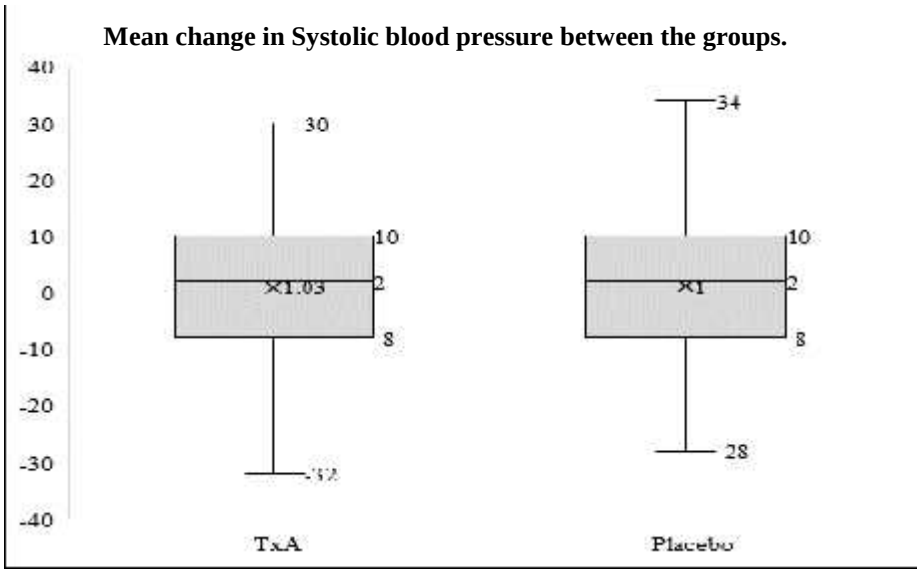
Systolic blood pressure(SBP)	TXA group	Placebo group	P value between groups
Pre intervention	111.81 ± 10.42	111.25 ± 9.30	0.65 [M]
Post intervention	112.84 ± 8.91	112.38 ± 8.08	0.66 [M]
Change	1.02 ± 12.57	1.12 ± 12.51	0.93 [M]
P value (within group)	0.25[W]	0.25 [W]	

[M] indicates Mann-Whitney U-test,[w] indicates Wilcoxon sign test

In the present study, the median of SBP was not significantly different between 2 groups at baseline as well as post intervention. There was no significant gain/reduction in SBP in both the groups. Mean change in SBP between the groups is depicted in table 11 and graph 11.

Graph - 11

Mean change in Systolic blood pressure between the groups.



Mean and median change of SBP in TxA group is almost similar as compared with the Placebo group.

Table-12

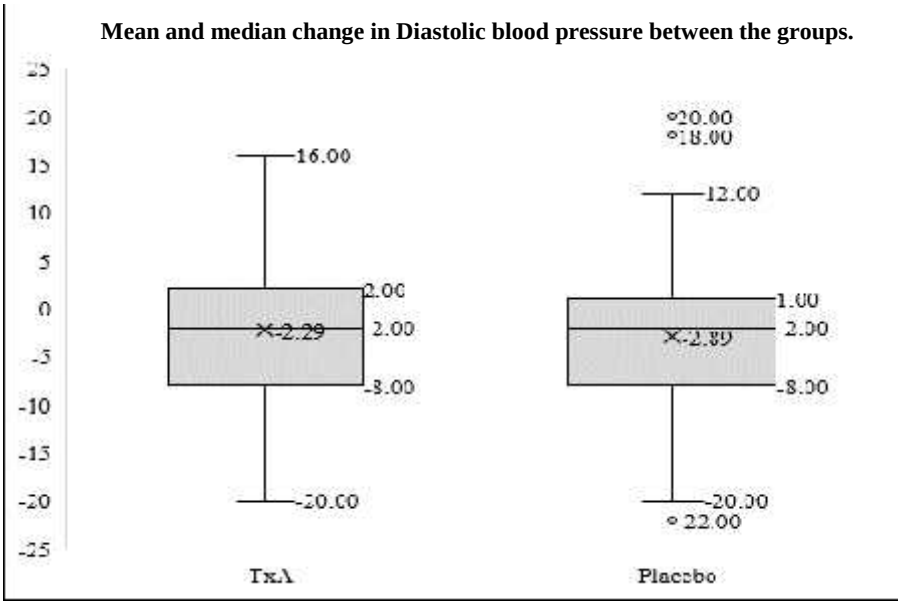
Mean change in Diastolic blood pressure(DBP)between the groups.

Diastolic blood pressure(DBP)	TXA group	Placebo group	P value between groups
Pre intervention	76.32 ± 5.87	75.40 ± 4.81	0.33 [M]
Post intervention	74.04 ± 5.79	72.52 ± 6.11	0.05 [M]
Change	-2.28 ± 7.50	-2.89 ± 7.98	0.71 [M]
P value (within group)	0.003 [W]	0.0004 [W]	

In the present study, the median of DBP was not significantly different between 2 groups at baseline as well as post intervention. However, it has been concluded that values of DBP significantly decreased during the intervention time in both the groups.Mean change in DBP between the groups is depicted in table 12 and graph12.

Graph-12

Mean and median change in Diastolic blood pressure between the groups.



Mean and median change of DBP in TxA group is almost similar as compared with the Placebo group.

Table-13

Incidence of minor adverse events in both groups

Minor adverse drug reactions	TXA group	Placebo group	Between groups P Value
Nausea	5 (4.76%)	4 (3.81%)	1
Vomiting	4(3.81%)	5 (4.76%)	1
dizziness	2(1.9%)	3 (2.86%)	1
Nausea + vomiting	2(1.9%)	1(0.95%)	1

In the present study, incidence of nausea was 4.76 % in the TXA group as compared to 3.81 % in the placebo group. The incidence of vomiting was 3.81 % in the TXA group and 4.76 % in the placebo group. Incidence of minor adverse events depicted in table 13 and graph 13

Graph 13

Incidence of minor adverse events in both groups

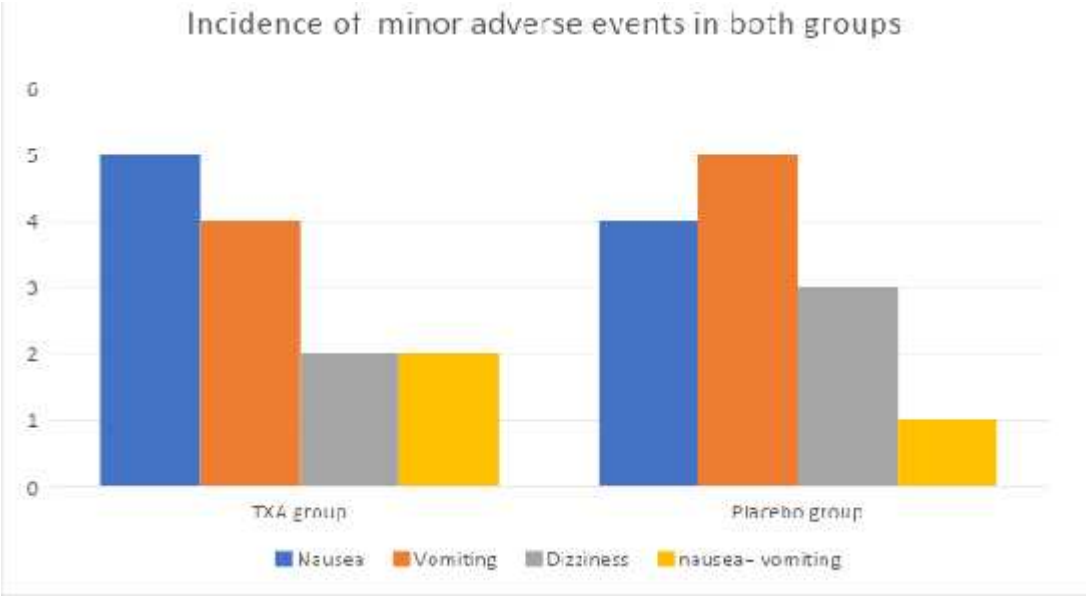


Table -14

Incidence of major adverse events in both groups

Adverse drug reactions	TXA group	Placebo group
Deep vein thrombosis	0	0
Pulmonary embolism	0	0
Myocardial infarction	0	0
Seizure episodes	0	0
Renal failure	0	0

In this study, there were no major adverse events in either of the groups as shown in table 14.

Table-15

Distribution based on duration of hospital stay

Duration of hospital stay	TXA group	Placebo group	P-value
</= 3 days	90 (85.7%)	85 (80.95%)	0.2
>3 days	15 (14.29%)	20 (19.05%)	

In this study, 85.71 % of the participant in TXA group had a hospital stay </= 3 days as compared to 80.95% in the placebo group, with a P value of 0.2.Distrubution based on duration of hospital stay is depicted in table 15 and graph 14.

Graph – 14

Distribution based on duration of hospital stay

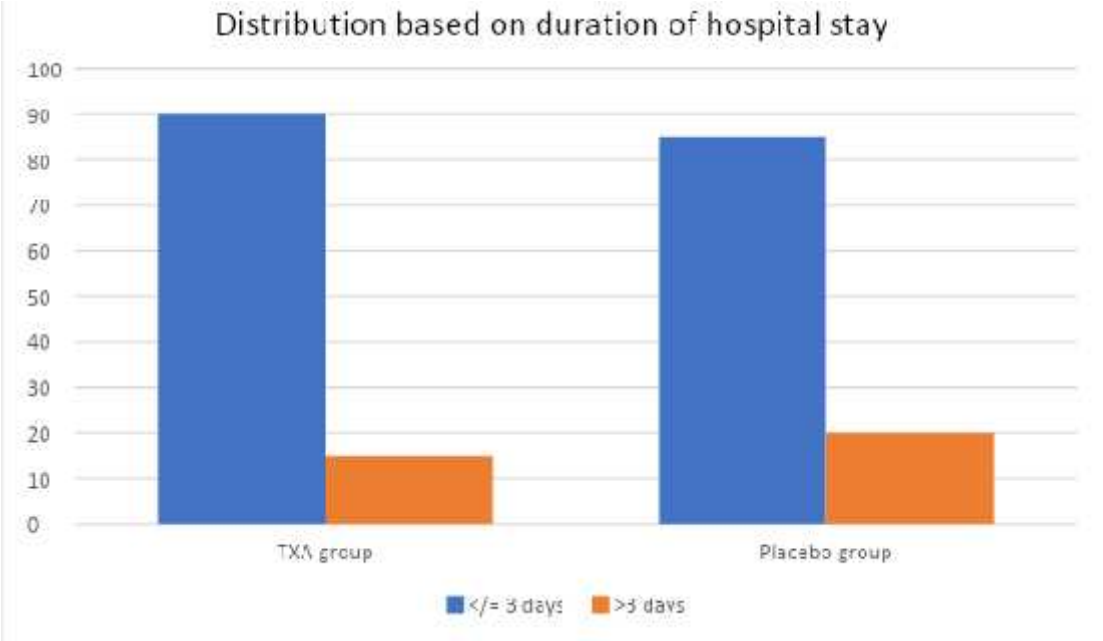


Table -16

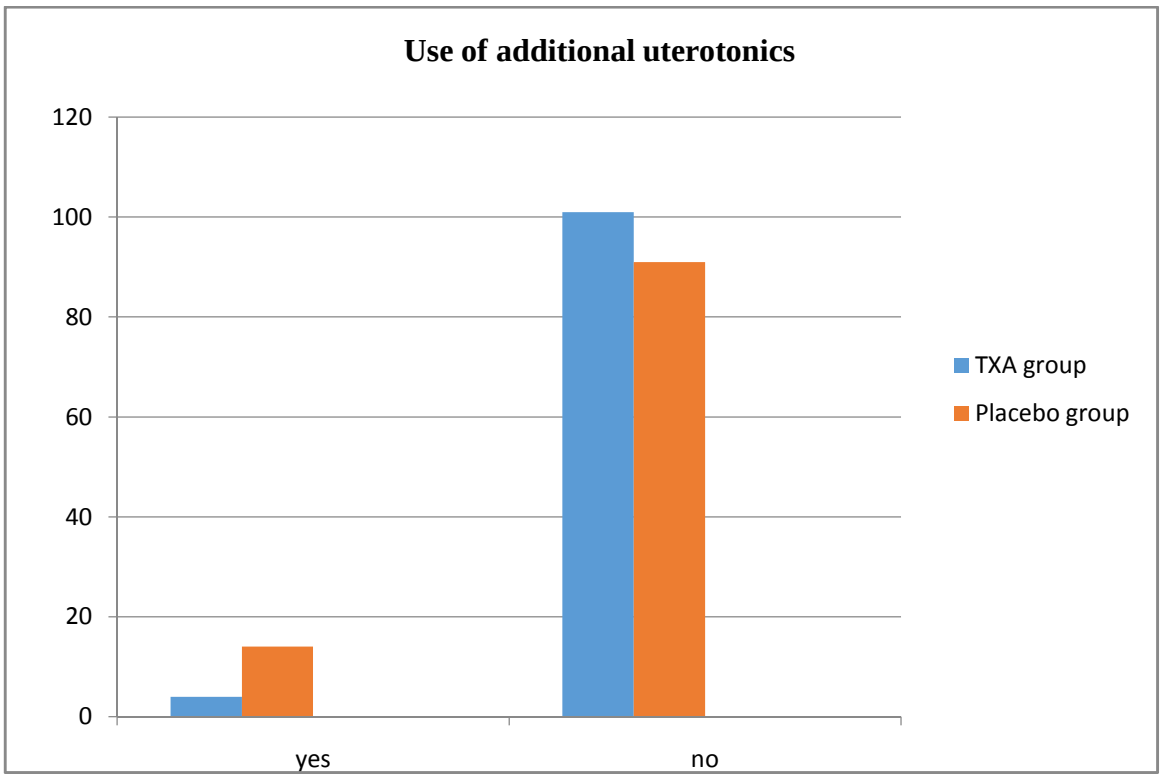
Use of additional uterotonics

Use of additional uterotonics	TXA group	Placebo group	P value
YES	4 (3.81%)	14 (13.33%)	0.02
NO	101(96.19%)	91 (86,67%)	

In this study, 3.81 % of participants in TXA group required additional uterotonics whereas 13.33% of participants in placebo group required additional uterotonics. Use of additional uterotonics depicted in table 16 and graph 15

Graph 15

Use of additional uterotonics



DISCUSSION

Obstetric haemorrhageremains to be the leading cause of maternal mortality and morbidity worldwide. Primary PPH has a global prevalence of 6%. Nearly 300,000 women die annually across the world from causes related to pregnancy with almost a quarter of these attributable to primary PPH. In high-income countries there is an increasing rate of primary PPH. In the low and middle income countries of Asia, primary PPH accounts for one third of all maternal deaths. [(2)] In addition to prophylactic uterotonic administration, an antifibrinolytic can be considered as a complementary component in the active management of third stage of labour.

TXA has been successfully used with positive effects in different clinical conditions. TXA has been shown to reduce the need for perioperative blood loss and transfusion in patients who undergo various surgeries. For women, TXA has been widely used to minimize blood loss and blood transfusion needs in the management of numerous gynecological clinical disorders, including menorrhagia, interventional surgical procedures such as cervical conization, and myomectomy. [(27)]

In the present study itwas observed that majority of the subjects in TXA and placebo group were of age group 18-22 years and 23-27 years respectively whereas the least number of subjects belonged to the age group of 33-37 years. It was concluded that the median of age was not significantly different between 2 groups in this study and both groups were matched for age.

In a study conducted by Yang H, Shi C-Department of Obst& Gynaecology, first teaching hospital of Beijing University, Beijing, China in 2001 october – the mean age was 23.5 years. [(28)]

In a similar study conducted by Yimeng Xia et al which included analysis of 4 trials searched through electronic databases in 2019, majority of the women belonged to the age group of 27- 30 years. [24]

In a study conducted by Priyankur Roy et al in the year 2015, on the role of TXA in reducing blood loss in vaginal delivery, the majority of women in both the groups belonged to 21-24 years of age.[29]

In the present study there was no significant difference in gravidity between the TXA group and placebo group. In a similar study conducted by Yildrium M.D at Erzincan military hospital, Turkey in April 2011 there was no significant difference in gravidity between the TXA group and placebo group. The two groups were matched for the gravida score.

In a similar study conducted by Priyankur Roy et al in the year 2015, on the role of TXA inreducing blood loss in vaginal delivery, theparity index was comparable in both the groups. [29]

In the present studymean BMIwas 18.5 - 24.9 kg/m2 in TXA group and placebo group. There was no difference in the BMI between the groups. In a similar study conducted by Shanghai International Pence maternity and child health hospital, Shanghai, China, therewas nosignificant difference in the mean BMI between the groups. In a study conducted by Priyankur Roy et al in the year 2015, on the role of TXA in reducing blood loss in vaginal delivery majority of the women had a BMI between 23-24 kg/m^2 , both groups were comparable. [29]

The present study showed that tranexamic acid significantly reduced the average blood loss as compared to placebo group.In the present study, the mean average blood loss was 250.10 ±133.54ml in the TXA group as compared to 334.2 ± 141.78ml in the placebo group with a P value of <0.0001 which was statistically significant.

Median loss was 200ml in TXA group which was less as compared with the Placebo group. 50% of participant had a blood loss between 150-300ml in the TXA group and the same in placebo group was 240-400ml.In a similar study conducted by the WOMAN trial showed the reduction in blood loss to be statistically highly significant in women who received tranexamic acid.[(1)] In a Study carried out by Ming-yingGai&coworkers in China showed tranexamic acid significantly reduces bleeding from the time of placental delivery to 2 hours postpartum. The study group showed total blood loss reduction by 30% as compared to control group. Findings of these studies correlated to the present study. [(28)]

Similarly, the CRASH 2 trial showed a significant reduction in mortality and bleeding in trauma patients receiving early TXA if administered over less than three hours. [(18)]. In a systematic search of electronic literature to review all studies looking at the use of tranexamic acid during pregnancy and puerperium a metanalysis on three randomized controlled trials showed that the blood loss after cesarean and vaginal births were found to be reduced by administration of tranexamic acid in absence of significant maternal and neonatal complications. [(27)]

In a similar study conducted by Howard et al administration of TXA to a theoretical cohort of 100,000 women receiving usual care for PPH prevented 403 maternal deaths due to haemorrhage and 457 laparotomies to control bleeding. [(30)]

In a Cochrane review of anti-fibrinolytic agents used for the treatment for post-partum haemorrhage identified three eligible trials, two of which compared intravenous tranexamic acid with placebo or standard care. A meta-analysis of 20,172 women from the WOMAN trial and French trial showed that tranexamic acid reduces the risk of death due to bleeding , with early treatment being more effective. [(18)]

It is interesting to note that in the present study tranexamic acid did not reduce the incidence of PPH significantly with an incidence of PPH in TXA and Placebo group to be 4.85% and 11.21% respectively, concluding that incidence of PPH was not significantly different between TXA and Placebo group in the present study..

In contrast to a Cochrane review on the use of prophylactic TXA for women with vaginal and caesarean birth, 3 trials from Turkey, Iran, and China studied the effectiveness and safety of TXA in 832 women who had a vaginal birth. Additionally, the incidence of PPH was also lower in the experimental group compared with that in the placebo control group. Similar to the present study estimated postpartum blood loss was significantly lower in the experimental group than in the placebo group. [(8)]

In the present study the need for blood transfusion, peripartum hysterectomy and arterial embolization was not significantly different between TXA and Placebo group. Although, postpartum transfusion was required for 9.8 % of the participants belonging to the placebo group as compared to the 3 % of participants in the TXA group, it was not statistically significant.

In a study conducted by the APA Xia on TXA for prevention of PPH in vaginal delivery which considered 4 trials, the number required transfusions showed no significant difference between the TXA and placebo groups in 2 trials [(24)]

In a study conducted by Franchini et carried out by the Italian National Blood Centre with the aim of promoting the nationwide implementation of Patient Blood Management, which performed an updated meta-analysis of the use of TXA in PPH , using the incidence of PPH as a primary outcome and mean blood loss volume , need for blood transfusion, and overall severe side effects related to TXA use as secondary outcomes. It was found that the need for transfusion was reduced in the TXA group when compared to control groups. [(30)]

In the present study, the median of pulse rate was not significantly different between 2 groups as well as post intervention and the median of gain in pulse rate was not significantly different between 2 groups.The median of SBP and DBP was not significantly different between 2 groups at baseline as well as post intervention. However, values of DBP significantly decreased during the intervention time in both the groups whereas there was no significant gain or reduction in SBP in both the groups.

In a similar study conducted by LeilaSekhavat et.al which enrolled 90 primipara's, it was noted that there was no significant alteration in the vital signs of subjects following tranexamic acid administration at time of delivery & at 1 hour & 2 hour postpartum. [31]

As opposed to a similar study conducted by Natalia Novikova et al in 2010, which showed a statistically significant change in vital parameters. [32]

In a study conducted by Priyankur Roy et al in the year 2015, on the role of TXA in reducing blood loss in vaginal delivery there was significant increase in pulse rate and decrease in blood pressure in the control group as compared to the placebo group. [29]

The side effects of tranexamic acid which included nausea, vomiting , dizziness were not statistically significant in both the groups in the present study. However inmetaanalysis conducted by Xia, Yimeng MD in the year 2020 two studies which included a total of 4164 patients reported the occurrence of nausea or vomiting, which was higher in the TXA treatment group than control group . In addition, 3 trialscompared nausea alone and the results showed that TXA resulted in increased incidence of nausea. The incidence of vomiting alone was analysed by 2 studies, and was higher in the TXA treatment group than the control group .[24]

The incidence of thrombosis during pregnancy & puerperium is 5-6 times higher than that in the general population. When the anti fibrinolytic drug tranexamic acid is administered, the increased risk of thrombosis should be considered.

Although previous studies evaluating the usage of TXA in oral, cardiac, and orthopaedic surgeries, and recent studies evaluating the usage of TXA in obstetrics confirmed its safety.[33], TXA can increase the risk of thromboembolic adverse effects. Most studies, including the meta-analyses and the WOMAN trial, showed no significant increase in thromboembolic events in women receiving low-dose TXA treatment. [5] These results were similar to the present study which showed no major adverse effects of TXA.Similarly the meta-analysis by Franchini et al. did not evidence an increase in serious side-effects, including thromboembolic events.

In the present study change in laboratory parameters that is Hb and PCV in TXA group was less as compared with the Placebo group and was significant. In a study conducted in the Department of obstetrics and gynaecology, University of Manitoba,2010, statistically significant drop in haemoglobin was observed in the control group.A double-blinded randomised controlled trial conducted by Gungorduk et al. on 228 women in Turkey comparing the effect of TXA to the placebo reported that the mean total blood were significantly less in the TXA group than that in the placebo group. The intervention group had higher mean haemoglobin and haematocrit levels than in the placebo group.[17] In a double-blind randomised controlled trial by Mojgan et al mean of hematocrit decline in the intervention group and in control group was statistically significant .[17]

In a study conducted by Priyankur Roy et al in the year 2015, on the role of TXA in reducing blood loss in vaginal delivery the post-deliveryhaemoglobin was significantly reduced in the control group as compared to the study group.[29]

In this study, 85.7 % of the participants in TXA group were discharged within 3 days of hospital admission whereas 80.95 % of participants in placebo group were discharged within 3 days of hospital admission. Duration of hospital stay was not statistically significant in this study.

In the present study, the need for additional uterotonics in the placebo group was significantly more than TXA group. This finding was similar to the study conducted by Priyankur Roy et al in the year 2015, on the role of TXA in reducing blood loss in vaginal delivery which demonstrated that need for additional uterotonics was statistically significant in the control group as compared to the study group.[29]

In a similar studyGungorduk and colleagues in 2010, additional uterotonics was used more in the placebo group than the TXA group and was statistically significant. results suggests that TXA, an antifibrinolytic which is easily available and cost effective can be recommended for use in vaginal deliveries, immediately after delivery of baby, as it has the potential to reduce the postpartum blood loss with no major adverse events.[17]In a meta-analysis performed by AsimAlam and Stephen Choi in the year 2015 which included Eighteen trials which concluded ,prophylactic TXA administration was associated with a reduction in use of uterotonics .[22]

CONCLUSION

Injection tranexamic acid, an antifibrinolytic agent when given prophylactically at the delivery of baby, by intravenous route reduces the blood loss during normal labour effectively without higher risk of severe adverse events. Routine use of TXA in obstetrics leads to reduced use of blood products, reduced need for surgical intervention, and decreased blood loss. TXA can be used as an adjunct to uterotonics in the third stage of labourdue to its clinical efficacy and safety to prevent PPH.

SUMMARY

In this randomized controlled trial conducted for a period of 1 year at KLE's DR. Prabhakar Kore Charitable Hospital, Belagavi a total of 210 subjects were recruited for the study consisting of 105 subjects in TXA group and 105 in placebo group. Both groups received routine care during the third stage of labor. Additionally the TXA group received 1 gram injection Tranexamic acid whereas the placebo group received normal saline. The amount of blood loss, change in hemoglobin and packed cell volume and adverse events were noted in both the groups.

- In this study, the two groups were matched for age, gravidity and body mass index.
- Incidence of PPH in TXA and Placebo group was 4.85% and 11.21% respectively and was not significantly different between the groups.
- The median of average blood loss was significantly less in TXA group.
- There was no statistical difference in the incidence of traumatic and atonic PPH between the groups.
- The median of gain in pulse rate was not significantly different between the groups.
- The median of SBP and DBP was not significantly different between the groups at baseline as well as post intervention.
- Median and mean change of Hb in TXA group was less as compared with the Placebo group and was statistically significant.
- Mean and median change of PCV in TXA group was less as compared with the Placebo groupand was statistically significant.
- Postpartum transfusion occurred in TXA group as compared with placebo group.

- Minor adverse effects which included nausea, vomiting and dizziness were not statistically significant between the groups.
- No major adverse events were noted in this study in either of the groups.
- No statistical difference in duration of hospital stay was noted in the 2 groups.
- Need for additional uterotonics was significantly lesser in the TXA group as compared to the placebo group.

BIBLIOGRAPHY

1. Vogel J, Oladapo O, Dowswell T, Gülmezoglu A. Updated WHO recommendation on intravenous tranexamic acid for the treatment of post-partum haemorrhage. The Lancet Global Health. 2018;6(1):e18-e19.
2. Kumar N. Postpartum Hemorrhage; a Major Killer of Woman: Review of Current Scenario. Obstetrics &Gynecology International Journal. 2016;4(4).
3. Sentilhes L, Daniel V, Darsonval A, Deruelle P, Vardon D, Perrotin F et al. Study protocol. TRAAP - TRAnexamic Acid for Preventing postpartum hemorrhage after vaginal delivery: a multicenter randomized, double-blind, placebo-controlled trial. BMC Pregnancy and Childbirth. 2015;15(1).
4. Sentilhes L, Lasocki S, Ducloy-Bouthors A, Deruelle P, Dreyfus M, Perrotin F et al. Tranexamic acid for the prevention and treatment of postpartum haemorrhage. British Journal of Anaesthesia. 2015;114
5. Shakur H, Roberts I, Fawole B, Chaudhri R, El-Sheikh M, Akintan A et al. Effect of early tranexamic acid administration on mortality, hysterectomy, and other morbidities in women with post-partum haemorrhage (WOMAN): an international, randomised, double-blind, placebo-controlled trial. The Lancet. 2017;389(10084):2105-2116.
6. Mielke R, Obermeyer S. The Use of Tranexamic Acid to Prevent Postpartum Hemorrhage. Journal of Midwifery & Women's Health. 2020;65(3):410-416.
7. Sentilhes L, Deneux-Tharaux C. Prophylactic tranexamic acid in addition to uterotonics may prevent blood loss for vaginal and caesarean deliveries. Evidence Based Medicine. 2016;21(3):97-97.
8. Novikova N, Hofmeyr G, Cluver C. Tranexamic acid for preventing postpartum haemorrhage. Cochrane Database of Systematic Reviews. 2015;.

9. Moodley J, Pattinson RC, Fawcus S, et al. The Confidential Enquiry into Maternal Deaths in South Africa: a case study. BJOG. 2014;121 Suppl 4:53-60.
10. Gallos I, Papadopoulou A, Man R, Athanasopoulos N, Tobias A, Price M et al. Uterotonic agents for preventing postpartum haemorrhage: a network meta-analysis. Cochrane Database of Systematic Reviews. 2018;.
11. Estcourt L, Desborough M, Brunskill S, Doree C, Hopewell S, Murphy M et al. Antifibrinolytics (lysine analogues) for the prevention of bleeding in people with haematological disorders. Cochrane Database of Systematic Reviews. 2016;.
12. Shakur H, Beaumont D, Pavord S, Gayet-Ageron A, Ker K, Mousa H. Antifibrinolytic drugs for treating primary postpartum haemorrhage. Cochrane Database of Systematic Reviews. 2018;.
13. Hibbs S, Roberts I, Shakur-Still H, Hunt B. Post-partum haemorrhage and tranexamic acid: a global issue. British Journal of Haematology. 2018;180(6):799-807.
14. Murdaca G, Greco M, Vassallo C, Gangemi S. Tranexamic acid adverse reactions: a brief summary for internists and emergency doctors. Clinical and Molecular Allergy. 2020;18(1).
15. WHO Recommendations for Active Management of the Third Stage of Labour AMSTL 2012
16. Khan, R., & El-Refaey, H. (2006). 13 Pathophysiology of Postpartum Hemorrhage and Third Stage of Labor.
17. Gungorduk K, Yıldırım G, Asıcıoğlu O, Gungorduk O, Sudolmus S, Ark C. Efficacy of Intravenous Tranexamic Acid in Reducing Blood Loss after Elective Cesarean Section: A Prospective, Randomized, Double-Blind, Placebo-Controlled Study. American Journal of Perinatology. 2010;28(03):233-240.

18. Effects of tranexamic acid on death, vascular occlusive events, and blood transfusion in trauma patients with significant haemorrhage (CRASH-2): a randomised, placebo-controlled trial. The Lancet. 2010;376(9734):23-32.
19. Morrison J. Military Application of Tranexamic Acid in Trauma Emergency Resuscitation (MATTERs) Study. Archives of Surgery. 2012;147(2):113.
20. Pabinger I, Fries D, Schöchl H, Streif W, Toller W. Tranexamic acid for treatment and prophylaxis of bleeding and hyperfibrinolysis. Wiener klinische Wochenschrift. 2017;129(9-10):303-316.
21. APA Ayedi, M.; Jarraya, A.; Smaoui, M.; Zouari, J.; Smaoui, L.; Kolsi, K. Effect of tranexamic acid on post partum hemorrhage by uterine atony: A preliminary result of a randomized, placebocontrolled trial, European Journal of Anaesthesiology: June 2011 - Volume 28 - Issue - p 165
22. Alam A, Choi S. Prophylactic Use of Tranexamic Acid for Postpartum Bleeding Outcomes: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. Transfusion Medicine Reviews. 2015;29(4):231-241.
23. Guideline Development Group Meeting on Updating the WHO recommendation on tranexamic acid for treatment of postpartum haemorrhage [Internet]. World Health Organization. 2020 [cited 16 September 2020]. Available from: https://www.who.int/reproductivehealth/topics/maternal_perinatal/gdg-tranexamic-acid/en/
24. Xia Y, Griffiths B, Xue Q. Tranexamic acid for postpartum hemorrhage prevention in vaginal delivery. Medicine. 2020;99(3):e18792.
25. Franchini M, Mengoli C, Cruciani M, et al. Safety and efficacy of tranexamic acid for prevention of obstetric haemorrhage: an updated systematic review and meta-analysis. Blood Transfus. 2018;16(4):329-337.

26. Ducloy-Bouthors A, Jude B, Duhamel A, Broisin F, Huissoud C, Keita-Meyer H et al. High-dose tranexamic acid reduces blood loss in postpartum haemorrhage. Critical Care. 2011;15(2):R117.
27. Peitsidis P, Kadir R. Antifibrinolytic therapy with tranexamic acid in pregnancy and postpartum. Expert Opinion on Pharmacotherapy. 2011;12(4):503-516.
28. Gai M, Wu L, Su Q, Tatsumoto K. Clinical observation of blood loss reduced by tranexamic acid during and after caesarian section: a multi-center, randomized trial. European Journal of Obstetrics &Gynecology and Reproductive Biology. 2004;112(2):154-157.
29. Roy P, Sujatha M, Bhandiwad A, Biswas B. Role of Tranexamic Acid in Reducing Blood Loss in Vaginal Delivery. The Journal of Obstetrics and Gynecology of India. 2016;66(S1):246-250.
30. Ker K, Roberts I, Chaudhri R, Fawole B, Beaumont D, Balogun E et al. Tranexamic acid for the prevention of postpartum bleeding in women with anaemia: study protocol for an international, randomised, double-blind, placebo-controlled trial. Trials. 2018;19(1).
31. Sekhavat L, Tabatabaii A, Dalili M, Farajkhoda T, Tafti A. Efficacy of tranexamic acid in reducing blood loss after cesarean section. The Journal of Maternal-Fetal& Neonatal Medicine. 2009;22(1):72-75.
32. Novikova N, Hofmeyr GJ. Tranexamic acid for preventing postpartum haemorrhage. Cochrane Database Syst Rev. 2010;(7):CD007872. Published 2010 Jul 7.
33. Li C, Gong Y, Dong L, Xie B, Dai Z. Is prophylactic tranexamic acid administration effective and safe for postpartum hemorrhage prevention?. Medicine. 2017;96(1):e5653.

34. Steer P. The surgical approach to postpartum haemorrhage. The Obstetrician & Gynaecologist. 2009;11(4):231-238.
35. Vogelzang R, Lindquist J. Pelvic Artery Embolization for Treatment of Postpartum Hemorrhage. Seminars in Interventional Radiology. 2018;35(01):041-047.
36. Levy J, Koster A, Quinones Q, Milling T, Key N. Antifibrinolytic Therapy and Perioperative Considerations. Anesthesiology. 2018;128(3):657-670.
37. Georgiev G, Tanchev P, Zheleva Z, Kinov P. Comparison of topical and intravenous administration of tranexamic acid for blood loss control during total joint replacement: Review of literature. Journal of Orthopaedic Translation. 2018; 13:7-12.
38. Chauncey JM, Wieters JS. Tranexamic Acid. [Updated 2020 Aug 11]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2020 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK532909/
39. Lee J, Reid R, Van Dijk J. P-008 Treatment of menorrhagia with tranexamic acid. Fertility and Sterility. 1997; 68:S96.
40. Kane I, Naseer Z, Jones L, Khanuja H, Sterling R. Safety of Tranexamic Acid. Techniques in Orthopaedics. 2017;32(1):28-33.
41. Pilbrant Å, Schannong M, Vessman J. Pharmacokinetics and bioavailability of tranexamic acid. European Journal of Clinical Pharmacology. 1981;20(1):65-72.
42. 13. Muhunthan K, Balakumar S, Navaratnaraja T, Premakrishna S, Arulkumaran S. Plasma Concentrations of Tranexamic Acid in Postpartum Women After Oral Administration. Obstetrics &Gynecology. 2020;135(4):945-948.
43. Goobie S, Frank S. Tranexamic Acid. Anesthesiology. 2017;127(3):405-407.

44. Lertbunnaphong T, Lapthanapat N, Leetheeragul J, Hakularb P, Ownon A. Postpartum blood loss: visual estimation versus objective quantification with a novel birthing drape. Singapore Med J. 2016;57(6):325-328.

ANNEXUREI.ETHICAL CLEARANCE.

K.L.E. ACADEMY OF HIGHER EDUCATION AND RESEARCH
(Deemed – to- be- University)
Accredited 'A' Grade by NAAC (2nd Cycle) Placed in Category 'A' by MHRD (GoI)
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Ref: MDC/DOME/57

Date: 24/11/2018

To.

REG. NO. BJ0118004

PG student in Obstetrics and Gynaecology,
J.N.Medical College,
BELAGAVI.

Sub: Institutional Ethical Clearance for the study.

With reference to the above, we wish to inform you that your proposed research project titled **"INJECTION TRANEXAMIC ACID FOR PREVENTING POSTPARTUM HEMORRHAGE AFTER VAGINAL DELIVERY: ONE YEAR HOSPITAL BASED RANDOMIZED, PLACEBO-CONTROLLED TRIAL"**, is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee on Human Subjects Research.

(Dr. Arathi Darshan)
Member Secretary
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

(Dr. Roopa M Bellad)
Chairman,
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

58

ANNEXURE II

CONSENT FOR PARTICIPATION IN RESEARCH STUDY

Mrs. _____ we are requesting you to enroll yourself in study titled **"**Injection tranexamic acid for preventing postpartum hemorrhage after vaginal delivery: one year hospital based randomized,placebo-controlled trial**"** conducted by **REG. NO. BJ0118004**, Post Graduate in M.S. Obstetrics and Gynecology under the guidance of DR._____Professor, Department of Obstetrics and Gynecology, J.N. Medical College, KAHER Belagavi.

The purpose of research study is to know the beneficial effects of tranexamic acid and its potentiality to reduce the amount of post partum blood loss. I will be the investigator for our study. This study is not being funded. I am going to give you information about this research project. Before you decide, you can talk to anyone you feel comfortable with about the research.

Purpose of study:

Bleeding after normal delivery is the most serious maternal complication in our country. Although there are different drugs to control the blood loss, there is a need for preventive management to reduce the amount of blood loss after normal delivery. This will also reduce the need for surgical procedures to stop the uncontrolled blood loss. This study will help us in knowing the effect of prophylactic use of injection tranexamic acid in reducing the amount of blood loss after a normal delivery.

Type of Study

This study is an interventional study. It involves administration of injection tranexamic acid or normal saline by intravenous route immediately after delivery and measurement of blood loss as well as follow up visits till 3rd month post delivery.

Participant selection

We are inviting all term pregnant women who visit our hospital for delivery to participate in this study.

Voluntary Participation

Your participation in research is voluntary. It is your choice whether to participate or not.Your decision whether to participate in the study or not will not change present or future health care services offered to you and will not affect your relationship with J.N. Medical College. If you choose not to participate in this study, you will still be offered the routine treatment to control the post delivery blood loss that is given at our hospital. You will continue to receive the routine post natal care at our hospital even if you decline to participate in this study. If you decide to participate you are free to withdraw at any time.

Information on the drug

The drug we are testing in this study is injection tranexamic acid which has been previously used for the treatment of excessive blood loss after delivery.The drug will be supplied from Sun Pharma Laboratories. We are using it in this study, as a preventive measure, to reduce the blood loss after delivery. You should know that this drug has a few side effects like nausea, vomiting, thrombosis.You will monitored every 15 minutes for first 2 hours to check for any side effects,you will be followed

upto 3 months post delivery to look for any of the side effects and appropriate treatment will be given for the same.

Some participants in this research will be given normal saline which is an inactive medicine also known as placebo medicine to compare the impact of tranexamic acid in controlling post partum blood loss. An inactive medicine or placebo medicine has no impact in controlling the post delivery blood loss. It is only being used in this study to know the beneficial impact of tranexamic acid. There is no risk associated with administration of normal saline.

Procedure Involved:

If you agree to enroll yourself in my study, your detailed past history will be taken to know if you are eligible for this study. If you have even one of the exclusion criteria you will not be enrolled into this study as your safety is the primary concern.

If you are eligible to participate in this study, after taking your consent you will be administered a drug either 1 gram tranexamic acid or placebo which is an inactive medicine which is 2 ml of normal saline by intravenous route immediately after the delivery of the baby, to study the impact of tranexamic acid on the post partum blood loss. Your blood test will be done on post delivery day 2, which involves withdrawing 2 ml of blood to check for the change in your blood parameters which are indicative of the benefits of the drug used.You will be followed upto the day of discharge to know if you required any additional treatment to control the blood loss. After discharge, you will be followed upto 3 months.

Side effects

As already mentioned there could be some adverse effects of this drug like

nausea, vomiting, thrombosis. If you develop any of adverse effects you will be treated for the same. In such a scenario we will discuss together and you will be consulted regarding whether you wish to continue in this study.

Risks

By participating in this research, there is a possibility that you will experience adverse effect of the drug. There is also a possibility that the drug may not work as well as we are expecting it to. If any of these conditions arise, you will be given the routine treatment which is offered at our hospital, for controlling the blood loss after delivery.

Benefits

The benefits of taking part in this research is your participation will help in reducing the amount of blood loss you have after delivery if you are administered tranexamic acid. Even if you are given the inactive or placebo medicine you will still be monitored for blood loss and given appropriate treatment if needed.

Your participation being valuable contribution to medical research to improvise treatment currently practiced in reducing the blood loss in the post delivery period and improve the maternal health.

Financial Incentives for participation:

No financial incentives are being offered to enrolled patients. It is purely being done with the idea of research and all the cost of the study will be borne by the investigator.

Privacy and Confidentiality:

The only people who will know that you are the research subject will be the members of the research team. No information about you or information provided by you during the research will be disclosed to others without your written permission except:

1. In emergency to protect your rights and welfare.
2. If required by law.

Authorization to Publish Results:

When the results of the research are published or discussed, in a conference, no information will be displayed that would disclose your identity. Any information that is obtained in connection with this study and that can be identified with you will remain confidential. Results of the study will be used to improve maternal outcome.

Right to refuse or withdraw from study:

You do not have to participate in this research if you do not wish to.You can withdraw at any time from the study. There will be no penalty for withdrawal. Your treatment and care in this hospital will not change irrespective of whether you agree to participate or not.You can be removed from the study if necessary.

Alternative:

You are free to withdraw yourself from this study at any point of time. You will continue to receive the routine post natal care even if you decline to participate in the study. Should you develop excessive postpartum bleeding you will be promptly treated for the same even if you have declined from the study. You will be informed about any new information that may affect your decision to participate in the study.

Institutional/sponsor's policy:

In the event of any injury related to the study, treatment will be made available through KAHER, Belagavi. There is no compensation or payment for such medical treatment by law. If you are injured you may contact REG. NO. BJ0118004, Post graduate student, Department of Obstetrics and Gynaecology, KAHER or by Ph. No: _____.

Contact details:

In case you have any questions related to the study, in future or in case of study related injury or illness, you can contact REG. NO. BJ0118004, Post graduate student, Department of Obstetrics and Gynecology, KAHER, Ph. No: _____or Dr. _____M.D(OBG), Professor, Dept. Of Obstetrics and Gynecology, KAHER Belagavi, Ph. No:_____.

If you have any queries about your rights as a study participant, you may contact Dr. Roopa M Bellad, Prof. of Pediatrics as Chairman of J. N. Medical College Institutional Ethics Committee on Human Subjects Research, Phone No.0831 2473777 ext-1527 at J. N. Medical College, Belagavi.

CONSENT STATEMENT:

I, _____ voluntarily agree for participating in this study. By signing this consent form I am not giving up any of my legal rights, I may withdraw from the study anytime. I am signing the consent form after having read or been read form in my own vernacular language, including the risks and the benefits and having all my questions answered.

Participant Name : _____

Signature of the Left Thumb Print of Participant : _____

Investigators Name: _____ Signature: _____

Witness Name : _____ Signature: _____

Date: _____

ತಳುವಳಿಕೆಯಿಸಮ್ಮತ

ರಸಚ್ಸ್ರ್ಡಿಶೀರ್ಷಿಕ:

"ಯೋನಿವಿತರಣೆಯನಂತರಪ್ರಸವದರಕ್ತಸ್ರಾವವನ್ನುತಡಯುವಇಂಜಕ್ಷನ್ಯಾನಕ್ಸಮಿಕ್ಆಸಿಡ್:
ಒಂದುವರ್ಷದಆಸ್ಪತ್ರೆಆಧಾರಿತಯಾದೃಚ್ಛಿಕ, ಪ್ಲೇಸ್ಬೊ-ನಿಯಂತ್ರಿತಪ್ರಯೋಗ"

ಪ್ರಧಾನತನಿಖಾಧಿಕಾರಿ: –

REG. NO. BJ0118004

ಸ್ನಾತಕೋತ್ತರಪದವಿ

ಪ್ರಸೂತಿಮತ್ತುಸ್ತ್ರೀರೋಗಶಾಸ್ತ್ರಇಲಾಖೆ,

ಜವನ್ಮಡಿಕಲ್ಕಾಲೇಜು, ಬೆಳಗಾವಿ

ಸಹ - ತನಿಖದಾರ

ಡಾ. _____

ಪ್ರೊಫೆಸರ್,

ಪ್ರಸೂತಿಮತ್ತುಸ್ತ್ರೀರೋಗಶಾಸ್ತ್ರಇಲಾಖೆ,

ಜವನ್ಮಡಿಕಲ್ಕಾಲೇಜ್, ಬೆಳಗಾವಿ

ಸಂಶೋಧನಾಅಧ್ಯಯನದಲ್ಲಿಪಾಲ್ಗೊಳ್ಳಲುಒಪ್ಪಿಗ

ಶ್ರೀಮತಿ _____

"ಯೋನಿಎತರಣಾನಂತರದರಕ್ತಸ್ರಾವವನ್ನುತಡಗಟ್ಟುವಲ್ಲಇಂಜಕ್ಷನ್ಟ್ರಾಕ್ಯಾಮಿಕ್ಆಮ್ಲ"

ಎಂಬಹಸರಿನಅಧ್ಯಯನದಲ್ಲಿನಿಮ್ಮನ್ನುತೊಡಗಿಸಿಕೊಳ್ಳಲುನಾವುಎನಂತಿಸುತ್ತಿದ್ದೇವ: **REG. NO. BJ0118004**, ಪೋಸ್ಟ್ಬ್ಯಜ್ಯುಯೇಟ್ನಲ್ಲಿನಡಸಿದಒಂದುವರ್ಷದಆಸ್ಪತ್ರೆಆಧಾರಿತಯಾದೃಚ್ಛಿಕ, ಪ್ಲೇಬೂ-ನಿಯಂತ್ರಿತಪ್ರಯೋಗ. ಎಂಎಸ

ಡಾ. _____ಪ್ರೊಫಸರ್, ಅಬ್ಸ್ಟ್ರೆಕ್ಷ್ಟ್ರುಜಿನಕಾಲಜಿವಿಭಾಗದಜ.ಎನ್. ಮಡಕಲ್ಕಾಲೇಜ್, ಬಳಗಾವಿಕಎಲ್ಇವಿಶ್ವವಿದ್ಯಾಲಯದಲ್ಲಿಬಳಗಾವಿಮಾರ್ಗದರ್ಶನದಲ್ಲಿಪ್ರಸೂತಿಮತ್ತುಗರ್ಭಶಾಸ್ತ್ರ.ಟಟ್ರಾನ್ಸ್ಕ್ಸಮಿಕ್ಆಮ್ಲದಪ್ರಯೋಜನಕಾರಿಪರಿಣಾಮಗಳನ್ನುಮತ್ತುಪೋಸ್ಟ್ಸಂಭಾವ್ಯರಕ್ತದನಷ್ಟವನ್ನುಕಡಿಮಮಾಡಲುಅದರಸಾಮರ್ಥ್ಯದಬಗ್ಗೆತಳಿಯುವುದುಸಂಶೋಧನಾಉದ್ದೇಶವಾಗಿದ.

ನಮ್ಮಅಧ್ಯಯನಕ್ಕನಾನುಶೋಧಕನಾಗಿರುತ್ತೇನ. ಈಅಧ್ಯಯನವುಹಣವನ್ನುಪಡಯುತ್ತಿಲ್ಲ. ನಾನುಈಸಂಶೋಧನಾಯೋಜನೆಯಬಗ್ಗೆಮಾಹಿತಿಯನ್ನುನೀಡಲುಹೋಗುತ್ತೇನ.

ನೀವುನಿರ್ಧರಿಸುವಮೊದಲು,

ನೀವುಸಂಶೋಧನೆಯಬಗ್ಗೆಹಾಯಾಗಿರುತ್ತಿದ್ದಯಾರಿಗಾದರೂಮಾತನಾಡಬಹುದು.

ಅಧ್ಯಯನದಉದ್ದೇಶ:

ಸಾಮಾನ್ಯಎತರಣಾನಂತರರಕ್ತಸ್ರಾವನಮ್ಮದೇಶದಲ್ಲಿಅತ್ಯಂತಗಂಭೀರತಾಯಿಯತೊಡಕು.

ರಕ್ತದನಿಯಂತ್ರಣವನ್ನುನಿಯಂತ್ರಿಸಲುವಿಭಿನ್ನಔಷಧಿಗಳಿವೆಯಾದರೂ,

ಸಾಮಾನ್ಯಎತರಣೆಯನಂತರರಕ್ತದಪ್ರಮಾಣವನ್ನುಕಡಿಮಗೊಳಿಸಲುತಡಗಟ್ಟುವನಿರ್ವಹಣೆಯಅಗತ್ಯವಿರುತ್ತದ.

ಅನಿಯಂತ್ರಿತರಕ್ತದನಷ್ಟವನ್ನುತಡಗಟ್ಟುವಸಲುವಾಗಿಶಸ್ತ್ರಚಿಕಿತ್ಸೆಯವಿಧಾನಗಳಅಗತ್ಯವನ್ನುಕಡಿಮಗೊಳಿ

ಸುತ್ತದ.

ಸಾಮಾನ್ಯಎತರಣಯನಂತರರಕ್ತದನಷ್ಟವನ್ನುಕಡಮೆಮಾಡುವಲ್ಲಿಇಂಜೆಕ್ಷನ್ಯಾನಕ್ಸಮಿಕ್ಅಮ್ಲದರೋಗನ

ರೋಧಕಬಳಕಯಪರಣಾಮವನ್ನು ತಿಳಿದುಕೂಳ್ಳುವಲ್ಲಿಈಅಧ್ಯಯನವುನಮಗಸಹಾಯಮಾಡುತ್ತದ .

ಅಧ್ಯಯನಪ್ರಕಾರ

ಈಅಧ್ಯಯನವುಒಂದುಮಧ್ಯಸ್ಥಕಯಅಧ್ಯಯನವಾಗಿದ.

ಇಂಜಕ್ಷನ್ಯಾನಕ್ಸಮಿಕ್ಆಸಿಡ್ಅಥವಾಸಾಮಾನ್ಯಲವಣಯುಕ್ತವುಎತರಣಾಮತ್ತುಬ್ಲೂಗಳನಷ್ಟದಅಳತಮ

ತ್ತುತಕ್ಷಣವೇ 3

ನೇತಿಂಗಳಪೂಸ್ಟ್ತರಣಾತನಕಭೇಟನೀಡುವನಂತರಇದುಒಳನಾಡಿನಮಾರ್ಗದಮೂಲಕಒಳಗೂಂಡಿರು

ತ್ತದ .

ಭಾಗವಹಿಸುವವರುಆಯ್ಕ

ಈಅಧ್ಯಯನದಲ್ಲಿಪಾಲ್ಗೂಳ್ಳಲುನಮ್ಮಆಸ್ಪತ್ರಗಭೇಟನೀಡುವಎಲ್ಲಾಗರ್ಭಿಣಮಹಿಳಯರನ್ನುನಾವುಆಹ್ವಾನ

ಸುತ್ತಿದ್ದೇವ .

ಸ್ವಯಂಪ್ರೇರತಭಾಗವಹಿಸುವಕ

ಸಂಶೋಧನಯಲ್ಲಿನಮ್ಮಭಾಗವಹಿಸುವಕಸ್ವಯಂಪ್ರೇರತವಾಗಿರುತ್ತದ.

ಭಾಗವಹಿಸುವಅಥವಾಇಲ್ಲವೇಎಂದುನಮ್ಮಆಯ್ಕಯಾಗಿದ.

ಅಧ್ಯಯನದಲ್ಲಿಪಾಲ್ಗೂಳ್ಳಬೇಕಅಥವಾಇಲ್ಲವೇನಮ್ಮನಿರ್ಧಾರವುಪ್ರಸ್ತುತಅಥವಾಭವಿಷ್ಯದಆರೋಗ್ಯಸೇವ

ಗಳನ್ನುನಮಗಬದಲಿಸುವುದಿಲ್ಲಮತ್ತುಜನ್ಮಡಕಲ್ಯಾಲೇಜ್ನೂಂದಿಗನನಮ್ಮಸಂಬಂಧದಮೇಲಪರಣಾಮ

ಬೀರುವುದಿಲ್ಲ. ಈಅಧ್ಯಯನದಲ್ಲಿಭಾಗವಹಿಸಬಾರದಂದುನೀವುಆರಿಸಿದರ,

ನಮ್ಮಆಸ್ಪತ್ರಯಲ್ಲಿನೀಡಲಾದಪೂಸ್ಟ್ನಲವರ bloos

ನಷ್ಟವನ್ನುನಿಯಂತ್ರಿಸಲುನೀವುಇನ್ನೂದಿನನಿತ್ಯದಚಿಕಿತ್ಸೆನೀಡಲಾಗುವುದು.

ಈಅಧ್ಯಯನದಲ್ಲಿಪಾಲ್ಗೊಳ್ಳಲುನೀವುನಿರಾಕರಿಸಿದರೂಸಹನಮ್ಮಆಸ್ಪತ್ರೆಯಲ್ಲಿವಾಡಿಕೆಯಪೋಸ್ಟ್ಟಾಲ್ಆ

ರೈಕೆಯನ್ನುನೀವುಪಡೆಯುತ್ತೀರಿ.

ನೀವುಭಾಗವಹಿಸಲುನಿರ್ಧರಿಸಿದರೆನೀವುಯಾವುದೇಸಮಯದಲ್ಲಿಹಿಂಪಡೆಯಲುಸ್ವತಂತ್ರರಾಗಿರುತ್ತಾರೆ.

ಔಷಧದಬಗ್ಗೆಮಾಹಿತಿ

ನಾವುಈಅಧ್ಯಯನದಲ್ಲಿಪರೀಕ್ಷಿಸುವಔಷಧಟ್ರಾನೆಕ್ಸಮಿಕ್ಆಮ್ಲವಾಗಿದೆ,

ಇದುಹಿಂದೆವಿತರಣೆಯನಂತರವಿಪರೀತರಕ್ತನಷ್ಟದಚಿಕಿತ್ಸೆಯಲ್ಲಿಬಳಸಲ್ಪಟ್ಟಿದೆ. ಈಅಧ್ಯಯನದಲ್ಲಿ,

ತಡಗಟ್ಟುವಿಕೆಯಅಳತೆಯಾಗಿ,

ವಿತರಣೆಯನಂತರರಕ್ತದನಷ್ಟವನ್ನುಕಡಿಮೆಮಾಡಲುನಾವುಅದನ್ನುಬಳಸುತ್ತೇವೆ. ಈಔಷಧಿಗೆವಾಕರಿಕೆ,

ವಾಂತಿ, ಥ್ರಂಬೋಸಿಸ್ಮತ್ತುಇತಾದಿಕಲವುಅಡ್ಡಪರಿಣಾಮಗಳುಉಂಟಾಗುತ್ತವೆಎಂದುನೀವುತಿಳಿದಿರಬೇಕು.

ಯಾವುದೇಅಡ್ಡಪರಿಣಾಮಗಳನ್ನುಪರಿಶೀಲಿಸಲುನೀವುಮೊದಲ 2 ಗಂಟೆಗಳಕಾಲಪ್ರತಿ 15

ನಿಮಿಷಗಳಲ್ಲೂಮೇಲ್ವಿಚಾರಣೆನಡೆಸುತ್ತೀರಿ, ಯಾವುದೇ 3

ತಿಂಗಳನಂತರದಬಿಟವಾಡಗನೀವುಅನುಸರಿಸುತ್ತೀರಿಅಡ್ಡಪರಿಣಾಮಗಳುಮತ್ತುಸರಿಯಾದಚಿಕಿತ್ಸೆಯನ್ನು

ನೀಡಲಾಗುವುದು.

ಈಸಂಶೋಧನೆಯಲ್ಲಿಭಾಗವಹಿಸುವಕಲವುಜನರಿಗೆಸಾಮಾನ್ಯಸಲೈನ್ನೀಡಲಾಗುವುದು.

ಇದುಪಾರ್ಶ್ವಪರಿಣಾಮಕಲ್ಪಿಸಲಾಗುವನಿಷ್ಕ್ರಿಯಔಷಧಿಯಾಗಿದ್ದು,

ಪಾರ್ಶ್ವಪರಿಣಾಮಕ್ತದನಷ್ಟವನ್ನುನಿಯಂತ್ರಿಸುವಲ್ಲಿಟ್ರಾನೆಕ್ಸಮಿಕ್ಆಮ್ಲದಪ್ರಭಾವವನ್ನುಹೋಲಿಸಬಹುದು.

ಪೋಸ್ಟ್ಪರಣ bloos

ನಷ್ಟವನ್ನುನಿಯಂತ್ರಿಸುವಲ್ಲಿನಿಷ್ಕ್ರಿಯಔಷಧಿಅಥವಾಪ್ಲಸೀಬೊಔಷಧಿಯಾವುದೇಪ್ರಭಾವಬೀರುವುದಿಲ್ಲ.

ಟ್ರಾನೆಕ್ಸಮಿಕ್ಆಮ್ಲದಪ್ರಯೋಜನಕಾರಿಪರಿಣಾಮವನ್ನುತಿಳಿಯಲುಈಅಧ್ಯಯನದಲ್ಲಿಮಾತ್ರಇದನ್ನುಬಳಸ

ಲಾಗುತ್ತದೆ. ಸಾಮಾನ್ಯಸಲೈನ್ಆಡಳಿತದಿಂದಿಗಯಾವುದೇಅಪಾಯವಿಲ್ಲ.

ಕಾರ್ಯವಿಧಾನಕ್ಕೆ ಒಳಪಟ್ಟದ :

ನೀವುನನ್ನ ಅಧ್ಯಯನದಲ್ಲಿ ನಿಮ್ಮನ್ನು ತೊಡಗಿಸಿಕೊಳ್ಳಲು ಒಪ್ಪಿಕೊಂಡರ,

ಈ ಅಧ್ಯಯನಕ್ಕಾಗಿ ನೀವು ಅರ್ಹರಾಗಿದ್ದರ ನಿಮ್ಮ ಎವರವಾದ ಹಿಂದಿನ ಇತಿಹಾಸವನ್ನು ತಿಳಿದುಕೊಳ್ಳ.

ನಿಮ್ಮ ಹೂರಗಿರುವ ಮಾನದಂಡವನ್ನು ಸಹ ನೀವು ಹೂಂದಿದ್ದರ ಈ ಸುರಕ್ಷತಗ ನೀವು ಸೇರ್ಪಡಗೂಳ್ಳುವುದಿಲ್ಲವಿ

ಕಂದರ ನಿಮ್ಮ ಸುರಕ್ಷತಯು ಪ್ರಾಥಮಿಕ ಕಾಳಜಿ. ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಪಾಲ್ಗೂಳ್ಳಲು ನೀವು ಅರ್ಹರಾಗಿದ್ದರ,

ನಿಮ್ಮ ಒಪ್ಪಿಗಯನ್ನು ತಗದುಕೂಂಡ ನಂತರ ನೀವು 1

ಗ್ಯಾಂಟ್ಯಾನಕ್ಸ ಮಿಕ್ ಆಸಿಡ್ ಅಥವಾ ಪ್ಲಸೀಬೂವನ್ನು ನಿಷ್ಕ್ರಿಯಗೂಳಿಸಲಾಗುತ್ತದ,

ಇದು ಮಗು ಎನ ಎತರಣಯ ನಂತರ ತಕ್ಷಣದ ಮದುಳಿನ 2 ಮಿಲೀ ಸಾಮಾನ್ಯ ಸಲೀನ್ ಒಳಕ,

ಪಾರ್ಶ್ವಮ್ಯಕ್ತನಷ್ಟದ ನಂತರ ಟ್ಯಾನಕ್ಸ ಮಿಕ್ ಆಮ್ಲದ ಪರಿಣಾಮವನ್ನು ಅಧ್ಯಯನ ಮಾಡಲು.

ನಿಮ್ಮ ರಕ್ತದ ಪರೀಕ್ಷಯು ಪೂಸ್ಟ್ ಲವರದಿನ 2 ರಂದು ನಡಯಲದ, ಇದರಲ್ಲಿ 2

ಮಿಲಿ ರಕ್ತವನ್ನು ಹಿಂತಗದುಕೂಳ್ಳುವುದು ನಿಮ್ಮ ರಕ್ತದ ನಯತಾಂಕಗಳಲ್ಲಿನ ಬದಲಾವಣಯನ್ನು ಪರಶೀಲಿಸಲು

ಬಳಸಲಾಗುತ್ತದ, ಇದು ಬಳಸದ ಔಷಧದ ಪ್ರಯೋಜನಗಳನ್ನು ಸೂಚಿಸುತ್ತದ.

ನೀವು ತಿಳಿದುಕೂಳ್ಳಲು ಡಿಸ್ಚಾರ್ಜ್ ನವನ್ನು ಅನುಸರಿಸುತ್ತೀರ ರಕ್ತನಷ್ಟವನ್ನು ನಿಯಂತ್ರಿಸಲು ನೀವು ಯಾವುದೇ ಹ

ಚ್ಚುವರ ಚಕತ್ಸಯನ್ನು ಬಯಸದಲ್ಲಿ. ಎಸರ್ಜನಯ ನಂತರ, ನಿಮಗ 3 ತಿಂಗಳವರಗ ಹಿಂತಿರುಗಬಹುದು .

ಅಡ್ಡ ಪರಿಣಾಮಗಳು

ಈಗಾಗಲೇ ಹೇಳಿದಂತ ವಾಕರಕ, ವಾಂತಿ,

ಥ್ರಂಬೋಸಿಸ್ ಮುಂತಾದ ಔಷಧಗಳಿಕಲವು ಪ್ರತಿಕೂಲ ಪರಿಣಾಮಗಳು ಇರಬಹುದು.

ನೀವು ಯಾವುದಾದರೂ ಪ್ರತಿಕೂಲ ಪರಿಣಾಮಗಳನ್ನು ಅಭಿವೃದ್ಧಿಪಡಿಸಿದರ,

ನೀವು ಅದರ ರತಿ ಚಕತ್ಸ ನೀಡುತ್ತೀರ.

ಅಂತಹಒಂದುಸನ್ನಿವೇಶದಲ್ಲಿನಾವುಒಟ್ಟಾಗಿಚರ್ಚಿಸುತ್ತೇವಮತ್ತುಈಅಧ್ಯಯನದಲ್ಲಿಮುಂದುವರಿಯಲುನೀ

ವುಬಯಸುತ್ತೀರೋಎಂದುನಿಮಗೆಸಮಾಲೋಚಿಸಲಾಗುತ್ತದ .

ಅಪಾಯಗಳು:

ಈಸಂಶೋಧನೆಯಲ್ಲಿಪಾಲ್ಗೊಳ್ಳುವಮೂಲಕ,

ಔಷಧದಪ್ರತಿಕೂಲಪರಿಣಾಮವನ್ನುನೀವುಅನುಭವಿಸುವಸಾಧ್ಯತೆಯಿದ.

ಔಷಧವುಕೆಲಸಮಾಡುವುದಿಲ್ಲಮತ್ತುನಾವುಅದನ್ನುನಿರೀಕ್ಷಿಸುತ್ತಿದ್ದೇವಎಂದುಸಹಸಾಧ್ಯವಿದ.

ಈಪರಿಸ್ಥಿತಿಗಳಲ್ಲಿಏನಾದರೂಉಂಟಾದರ,

ನಮ್ಮಆಸ್ಪತ್ರೆಯಲ್ಲಿನೀಡಲಾಗುವದಿನನಿತ್ಯದಚಿಕಿತ್ಸೆಯನ್ನುನೀಡಲಾಗುವುದು,

ಏತರಣೆಯನಂತರರಕ್ತದನಷ್ಟವನ್ನುನಿಯಂತ್ರಿಸಲು .

ಪ್ರಯೋಜನಗಳು

ಈಸಂಶೋಧನೆಯಲ್ಲಿಪಾಲ್ಗೊಳ್ಳುವಪ್ರಯೋಜನಗಳುನಿಮ್ಮಟ್ರಾನ್ಸಿಕ್ಯಾಮಿಕ್ಆಸಿಡ್ಅನ್ನುನೀಡಿದರನಿಮ್ಮ

ಭಾಗವಹಿಸುವಿಕೆಯುಏತರಣೆಯನಂತರನೀವುಹೊಂದಿರುವರಕ್ತದಪ್ರಮಾಣವನ್ನುಕಡಿಮೆಮಾಡಲುಸಹಾ

ಯಮಾಡುತ್ತದ. ನೀವುನಿಷ್ಕ್ರಿಯಅಥವಾಪ್ಲಸೀಬೊಔಷಧನೀಡಲಾಗಿದ್ದರೂಸಹ,

ನೀವುಇನ್ನೂರಕ್ತದನಷ್ಟಕ್ಕಮೇಲ್ವಿಚಾರಣೆಮಾಡಲಾಗುವುದುಮತ್ತುಅಗತ್ಯವಿದ್ದರಸರಿಯಾದಚಿಕಿತ್ಸೆನೀಡಲಾ

ಗುವುದು .

ಪೋಸ್ಟ್ ಏತರಣೆಅವಧಿಯಲ್ಲಿರಕ್ತದನಷ್ಟವನ್ನುಕಡಿಮೆಮಾಡಲುಮತ್ತುತಾಯಿಯಆರೋಗ್ಯವನ್ನುಸುಧಾರಿಸ

ಲುಪ್ರಸ್ತುತಚಿಕಿತ್ಸೆಯನ್ನುಸುಧಾರಿಸಲುವೈದ್ಯಕೀಯಸಂಶೋಧನೆಗೆಅಮೂಲ್ಯಕೊಡುಗೆನೀಡುವುದುನಿಮ್ಮನಿಮ್ಮ

ಭಾಗವಹಿಸುವಿಕೆ .

ಭಾಗವಹಿಸುವಿಕೆಗಾಗಿಹಣಕಾಸಿನಉತ್ತೇಜಕಗಳು:

ನೋಂದಾಯಿತರೋಗಿಗಳಿಗೆಹಣಕಾಸಿನಉತ್ತೇಜನನೀಡಲಾಗುವುದಿಲ್ಲ.

ಇದುಕೇವಲಸಂಶೋಧನೆಯಪರಿಕಲ್ಪನೆಯೊಂದಿಗೆಮಾಡಲ್ಪಟ್ಟಿದೆಮತ್ತುಅಧ್ಯಯನದಎಲ್ಲಾವಚ್ಚವನ್ನುತನಿಖ

ದಾರರುಹೊಂದುತ್ತಾರೆ.

ಗೌಪ್ಯತೆಮತ್ತುಗೋಪ್ಯತೆ:

ನೀವುಸಂಶೋಧನಾವಿಷಯವೆಂದುತಿಳಿಯುವವಿಷಯಕಜನರುಸಂಶೋಧನಾತಂಡದಸದಸ್ಯರಾಗಿದ್ದಾರೆ.ಹೊ

ರತುಪಡಿಸಿನಿಮ್ಮಲಿಖಿತಅನುಮತಿಯಿಲ್ಲದೆಯೇಸಂಶೋಧನೆಯಸಮಯದಲ್ಲಿನಿಮಗೆಅಥವಾಮಾಹಿತಿಯಬ

ಗ್ಗೆಯಾವುದೇಮಾಹಿತಿಯುಬಹಿರಂಗಗೊಳ್ಳುವುದಿಲ್ಲ:

1. ನಿಮ್ಮಹಕ್ಕುಗಳನ್ನುಮತ್ತುಕಲ್ಯಾಣವನ್ನುರಕ್ಷಿಸಲುತುರ್ತುಪರಿಸ್ಥಿತಿಯಲ್ಲಿ.

2. ಕಾನೂನಿನಿಂದಅಗತ್ಯವಿದ್ದರೆ.

ಫಲಿತಾಂಶಗಳನ್ನುಪ್ರಕಟಿಸಲುಅಧಿಕಾ :

ಸಂಶೋಧನೆಯಫಲಿತಾಂಶಗಳನ್ನುಪ್ರಕಟಿಸಿದಾಗಅಥವಾಚರ್ಚಿಸಿದಾಗ, ಒಂದುಸಮ್ಮೇಳನದಲ್ಲಿ,

ನಿಮ್ಮಗುರುತನ್ನುಬಹಿರಂಗಪಡಿಸುವಯಾವುದೇಮಾಹಿತಿಯನ್ನುಪ್ರದರ್ಶಿಸಲಾಗುವುದಿಲ್ಲ.

ಈಅಧ್ಯಯನಕ್ಕೆಸಂಬಂಧಿಸಿದಂತಪಡೆದಮತ್ತುನಿಮ್ಮೊಂದಿಗೆಗುರುತಿಸಬಹುದಾದಯಾವುದೇಮಾಹಿತಿಗೌ

ಪ್ಯವಾಗಿರುತ್ತದೆ.

ತಾಯಿಯಫಲಿತಾಂಶವನ್ನುಸುಧಾರಿಸಲುಅಧ್ಯಯನದಫಲಿತಾಂಶಗಳನ್ನುಬಳಸಲಾಗುತ್ತದೆ.

ಅಧ್ಯಯನದಿಂದನಿರಾಕರಿಸುವಅಥವಾಹಿಂದಕ್ಕೆಹೋಗುವಹಕ್ಕು :

ನೀವುಬಯಸಿದಿದ್ದರೆಈಸಂಶೋಧನೆಯಲ್ಲಿಪಾಲ್ಗೊಳ್ಳಬೇಕಾಗಿಲ್ಲ.ನೀವುಅಧ್ಯಯನದಿಂದಯಾವುದೇಸಮಯ

ದಲ್ಲಿಹಿಂತೆಗೆದುಕೊಳ್ಳಬಹುದು. ವಾಪಸಾತಿಗೆಯಾವುದೇದಂಡವಿಲ್ಲ.

ಥಿಸೋಸ್ಫಾಟಲ್ಲಿರುವನಿಮ್ಮಚಿಕಿತ್ಸೆಮತ್ತುಕಾಳಜಿಯುನೀವುಭಾಗವಹಿಸಲುಅಥವಾಒಪ್ಪಿಕೊಳ್ಳುತ್ತಿದ್ದಯೇ

ಹೊರತುಬದಲಾಗುವುದಿಲ್ಲ. ಅಗತ್ಯವಿದ್ದರೆನೀವುಅಧ್ಯಯನದಿಂದಹಿಂತೆಗೆದುಹಾಕಬಹುದು.

ಪರ್ಯಾಯ:

ಈಅಧ್ಯಯನದಿಂದನಿಮ್ಮನ್ನುಯಾವಸಮಯದಲ್ಲಾದರೂಹಿಂತೆಗೆದುಕೊಳ್ಳಲುನೀವುಮುಕ್ತರಾಗಿದ್ದೀರಿ.

ನೀವುಅಧ್ಯಯನದಲ್ಲಿಪಾಲ್ಗೊಳ್ಳಲುನಿರಾಕರಿಸಿದರೂಸಹವಾಡಿಕೆಯಪೋಸ್ಟ್ ಟಾಲ್‌ಆರೈಕೆಯನ್ನುನೀವುಸ್ವೀ

ಕರಿಸುತ್ತೀರಿ.

ನೀವುಅಧ್ಯಯನದಿಂದನಿರಾಕರಿಸಿದರೂಸಹನೀವುತೀವ್ರವಾಗಿಪ್ರಸವಾನಂತರದರಕ್ತಸ್ರಾವವನ್ನುಬಳಸಿಕೂ

ಳ್ಳಬೇಕು.

ಅಧ್ಯಯನದಲ್ಲಿಪಾಲ್ಗೊಳ್ಳುವನಿಮ್ಮನಿರ್ಧಾರದಮೇಲೆಪರಿಣಾಮಬೀರುವಯಾವುದೇಹೊಸಮಾಹಿತಿಯಕುರಿ

ತುನಿಮಗೆತಿಳಿಸಲಾಗುವುದು.

ಸಾಂಸ್ಥಿಕ / ಪ್ರಾಯೋಜಕರನೀತಿಗಳು:

ಅಧ್ಯಯನಕ್ಕೆಸಂಬಂಧಿಸಿದಯಾವುದೇಗಾಯದಸಂದರ್ಭದಲ್ಲಿ, ಕಾಹರ್,

ಬೆಳಗಾವಿಮೂಲಕಚಿಕಿತ್ಸೆಲಭ್ಯವಾಗುತ್ತದೆ.

ಕಾನೂನಿನಮೂಲಕಇಂತಹವೈದ್ಯಕೀಯಚಿಕಿತ್ಸೆಗಯಾವುದೇಪರಿಹಾರಅಥವಾಪಾವತಿಇಲ್ಲ.

ನೀವುಗಾಯಗೊಂಡರೆಡಾ. _____, ಪೋಸ್ಟ್‌ಡಾಕ್ಟರಲ್‌ವಿದ್ಯಾರ್ಥಿ,

ಪ್ರಸೂತಿಮತ್ತುಸ್ತ್ರೀರೋಗಶಾಸ್ತ್ರವಿಭಾಗ, ಕಾಹರ್‌ಅಥವಾದೂರವಾಣಿಸಂಖ್ಯೆ: _____.

ಸಂಪರ್ಕವಿವರಗಳು:

ಭವಿಷ್ಯದಲ್ಲಿಅಥವಾಅಧ್ಯಯನದಸಂಬಂಧಿತವಾಗಿಅಥವಾಅನಾರೋಗ್ಯದಸಂದರ್ಭದಲ್ಲಿನೀವುಅಧ್ಯಯನ

ಕ್ಕೆಸಂಬಂಧಿಸಿದಯಾವುದೇಪ್ರಶ್ನೆಗಳನ್ನುಹೊಂದಿದ್ದರೆ, **REG. NO. BJ0118004**,

ಪೋಸ್ಟ್‌ಡಾಕ್ಟರಲ್‌ವಿದ್ಯಾರ್ಥಿ, ಪ್ರಸೂತಿಮತ್ತುಸ್ತ್ರೀರೋಗಶಾಸ್ತ್ರಇಲಾಖೆ,

ಕೆ.ಎಲ್.ಇಆಸ್ಪತ್ರೆಮತ್ತುಎಮ್‌ಆರ್‌ಸಿ, ದೂರವಾಣಿಸಂಖ್ಯೆ: _____ಅಥವಾಡಾ.

ಕಮಲ್ಪ.ಪಾಟೀಲ್‌ಎಂ.ಡಿ (ಒಬಿಜಿ), ಪ್ರೊಫೆಸರ್, ಪ್ರಸೂತಿಮತ್ತುಸ್ತ್ರೀರೋಗಶಾಸ್ತ್ರವಿಭಾಗ,

ಕೆಎಲ್‌ಇಎಸ್‌ಆಸ್ಪತ್ರೆಮತ್ತುಎಮ್‌ಆರ್‌ಸಿ, ಕಾಹರ್‌ಬೆಳಗಾವಿ, ದೂರವಾಣಿಸಂಖ್ಯೆ: _____.

ಅಧ್ಯಯನದಲ್ಲಿನಿಮ್ಮಭಾಗವಹಿಸುವಿಕಸ್ವಯಂಪ್ರೇರಿತವಾಗಿರುತ್ತದ.

ಅಧ್ಯಯನದಪಾಲ್ಗೊಳ್ಳುವವರಾಗಿನಿಮ್ಮಹಕ್ಕುಗಳಕುರಿತುನಿಮಗಹಚ್ಚಿನಮಾಹಿತಿಬೇಕಾದಲ್ಲಿ,

ನೀವುಮಾನವವಿಷಯಗಳಸಂಶೋಧನಯಜವನ್ನುಡಿಕಲ್ಕಾಲೇಜ್ಆಫ್ನರ್ಸಿಂಗ್ಎಜುಕೇಷನಲ್ಎಫಿಕ್ಸ್ಮಿಟಿಯಅಧ್ಯಕ್ಷ

ರಾಗಿದ್ದಡಾ. ರೂಪಾಎಂಬಲ್ಲಾಡ್, ಪ್ರೊಫಸರ್ಆಫ್ಪೀಡಿಯಾಟ್ರಿಕ್ಸ್, ದೂರವಾಣಿಸಂಖ್ಯ .0831 2473777

ಎಕ್ಸ್ಟ್ -1527 ನಲ್ಲಿಸಂಪರ್ಕಿಸಬಹುದು.

ಒಪ್ಪಿಗಪತ್ರ

ನಾನು, _____

ಈಅಧ್ಯಯನದಲ್ಲಿಪಾಲ್ಗೊಳ್ಳಲುಸ್ವಯಂಪ್ರೇರಣಯಿಂದಒಪ್ಪುತ್ತೇನ.ಈಸಮ್ಮತಿಯನಮೂನಯಲ್ಲಿಸಹಿಹಾಕು

ವಮೂಲಕನನ್ನಯಾವುದೇಕಾನೂನುಹಕ್ಕುಗಳನ್ನುನಾನುಬಿಡುತ್ತಿಲ್ಲ,

ನಾನುಯಾವಸಮಯದಲ್ಲಾದರೂಅಧ್ಯಯನವನ್ನುಹಿಂತಗೆದುಕೊಳ್ಳಬಹುದು.ನನ್ನಸ್ವಂತದೇಶೀಯಭಾಷ

ಯಲ್ಲಿಒದಿದನಂತರಅಥವಾಫಾರ್ಮ್ಅನ್ನುಒದಿದನಂತರನಾನುಒಪ್ಪಿಗಫಾರ್ಮ್ಗೆಸಹಿಹಾಕುತ್ತಿದ್ದೇನ,

ಅಪಾಯಗಳುಮತ್ತುಪ್ರಯೋಜನಗಳನ್ನುಒಳಗೊಂಡಂತಮತ್ತುನನ್ನಎಲ್ಲಪ್ರಶ್ನಗಳಿಗಉತ್ತರಿಸಿದ.

ಭಾಗವಹಿಸುವವರು: _____

ಪಾಲ್ಗೊಳ್ಳುವವರಎಡಗೈಹೆಬ್ಬೆರಳಿನಸಹಿ: _____

ತನಿಖಾಧಿಕಾರಿಗಳುಹಸರು: _____ ಸಹಿ: _____

ಎಟ್ನೆಸ್ಟರು: _____ ಸಹಿ: _____

ದಿನಾಂಕ: _____

माहितीपूर्णसंमती

संशोधनअभ्यासाचेशीर्षक:

"योनिडिलीव्हरीनंतरपोस्टपर्टमहेमोरेजचीरोकथामकरण्यासाठीइंजेक्शनट्रनेक्सॅमिकॲसिडःए

कवर्षोचाहॉस्पिटलआधारितयादृच्छिक, प्लेसबो-नियंत्रितचाचण "

मुख्यअन्वेषक: -

REG. NO. BJ0118004

पदव्युत्तरपदवी

प्रसूतिवस्त्रीविज्ञानविभाग,

जेएनमेडिकलकॉलेज, बेलगवी

सह-अन्वेषक:

डॉ. _____

प्राध्यापक,

प्रसूतिवस्त्रीविज्ञानविभाग,

जेएनमेडिकलकॉलेज, बेलगवी

संशोधनअभ्यासातसहभागघेण्यासाठीमान्यता

श्रीमती _____

आम्हीयोनिअलडिलीव्हरीनंतरपोस्टपार्टमहेमोरेजथांबविण्याकरिताइंजेक्शनट्रॅनेक्सॅमिकॲसिडनावाच्याअभ्यासामध्येस्वतःलानावनोंदणीकरण्यासविनंतीकरीतआहोत:

एकवर्षहॉस्पिटलआधारितयादृच्छिक, प्लेसबो-नियंत्रितचाचणी"REG. NO. BJ0118004, एम.एस.मधीलपदव्युत्तरपदवीधर.डॉ._____प्राध्यापक, ओबस्टेट्रिक्सआणिगिनॅकोलॉर्ज, जे.एन.मेडिकलकॉलेज, के एलईयुनिव्हर्सिटी, बेलगवीच्याअंतर्गतबेळगाव,

यांच्यामार्गदर्शनाखालीओबस्टेट्रिक्सआणिगायनॉकॉलॉजी.ट्रॅनेक्सॅमिकऍसिडचेफायदेकारकप्र

भावआणिपोस्टपार्टमरक्तसंक्रमणकमीकरण्याच्यासंभाव्यतेचेसंशोधनसंशोधनअभ्यासाचेहेतू आहे.मीआमच्याअभ्यासासाठीचौकशीकरणारआहे.याअभ्यासाचानिधीयेतनाही.मीयासंशोधन प्रकल्पाबद्दलमाहितीदेणारआ .आपणनिर्णयघेण्यापूर्वी, आपणसंशोधनासहसहजतेनेकोणालाहीबोलूशकता.

अभ्यासाचाउद्देशः

सामान्यप्रसारानंतररक्तस्त्रावहाआपल्यादेशातीलसर्वातगंभीरमातृसमस्याआहे. रक्तदाबनियंत्रितकरण्यासाठीविविधऔषधेआहेततरी, सामान्यवितरणानंतररक्ताच्यानुकसानीचीमात्राकमीकरण्यासाठीप्रतिबंधात्मकव्यवस्थापन आवश्यकआहे. यामुळेअनियंत्रितरक्ततोटाथांबविण्यासाठीशल्यक्रियेच्याप्रक्रियेचीआवश्यकतादेखीलकमीहोई ल. सामान्यअभ्यासानंतररक्ताचातोटाकमीकरण्यासाठीइंजेक्शनट्रॅनेक्सॅमिकॲसिडच्याप्रोफेले क्टिकवापराचाप्रभावजाणूनघेण्यातयाअभ्यासामुळेआम्हालामदतहोईल .

अभ्यासप्रकार

हाअभ्यासएकहस्तक्षेपअभ्यासआ . यातडिझेलनंतरलगेचचइंजेक्शनट्रॅनेक्सॅमिकऍसिडकिंवासामान्यलवणानेइंट्राव्हेनसमार्गानेब्लू ओसनुकसानतसेचतिसऱ्यामहिन्याच्यापोस्टडिलिव्हरीपर्यंतफॉलोअपभेटींचासमावेशअसतो .

सहभागीनिवड

आम्हीयाअभ्यासातभागघेण्यासाठीआपल्याहॉस्पिटललाभेटदेणाऱ्यासर्वगर्भवतीमहिलांनाआमं त्रितकरीतआहोत .

स्वयंसेवीसहभाग

संशोधनमध्येआपलेसहभागस्वैच्छिकआहे.सहभागीव्हायचेआहेकिवानाहीहेआपल्यानिवडीचे आहे.अभ्यासातसहभागीव्हायचेआहेकिंवानाहीहेआपल्यानिर्णयामुळेआपल्यालादिलेलीवर्तमा नकिंवाभविष्यातीलआरोग्यसेवासेवाबदलणारनाहीतआणिजे.एन.शीआपल्यानातेसंबंधावरको णताहीपरिणामहोणारनाही.

वैद्यकीयमहाविद्यालयजरआपणयाअभ्यासातभागनघेण्याचेनिवडलेतरआपल्यालाअद्याप आमच्यारुग्णालयातदिल्याजाणाऱ्यापोस्टडिलिव्हरीब्लूओसहानीनियंत्रितकरण्यासाठीनियमि तउपचारकेलेजातील.

जरीआपणयाअभ्यासातभागघेण्यासनकारदिलातरीहीआपणआमच्याहॉस्पिटलमध्येनियमित पोस्टनेटलकेअरघेऊशकता.

आपणसहभागीहोण्याचेठरविल्यासआपणकोणत्याहीवेळीमागेघेण्यासमोकळेआहात.

औषधमाहिती

आम्हीयाअभ्यासातचाचणीघेतअसलेल्याऔषधानेट्रॅनेक्सॅमिकॲसिडआहेज्याचापूर्वीवितरणा नंतरअतिरक्तरक्तदाबहोण्याच्याप्रक्रियेसाठीवापरलागेलाआहे.

डिलीव्हरीनंतररक्ततोटाकमीकरण्यासाठी, आम्हीयाअभ्यासामध्ये, प्रतिबंधात्मकउपायम्हणूनवापरतआहोत.

आपल्यालाहेमाहितअसलेपाहिजेकीयाऔषधानेमळमळ, उलट्या, थ्रोम्बोसिससारख्याकाहीसाइडइफेक्ट्सआहेत.

आपणकोणत्याहीदुष्परिणामांचीतपासणीकरण्यासाठीपहिल्या 2 तासांकरिताप्रत्येक 15 मिनिटांचेपरीक्षणकेलेजाईल, आपल्यालाकोणत्याहीमहिन्यासाठी 3 महिन्यांनंतरपोस्टवितरणकेलेजाईलसाइडइफेक्ट्सआणियोग्यउपचारत्यासाठीदिलेजातील.

यासंशोधनातीलकाहीसहभागींनासामान्यखारटपणादिलाजाईलजोऍक्टिव्हडायरेक्टआहेज्या लाप्लेसबोऔषधेम्हणूनओळखलेजातेजेणेकरूनट्रॅनेक्सॅमिकॲसिडच्यापरिणामीरक्तसंक्रमणा सनियंत्रणातठेवण्यातप्रभावपड .

पोस्टडिलीव्हरीब्लूओसहानीनियंत्रितकरण्यासाठीएकनिष्क्रियऔषधकिंवाप्लेसबोऔषधांचाकं णताहीप्रभावनाही.ट्रॅनेक्सॅमिकऍसिडचेफायदेशीरप्रभावजाणूनघेण्यासाठीयाअभ्यासातकेवळया चावापरकेलाजातआहे.सामान्यखारटपणाच्याव्यवस्थापनासहकोणताहीधोकानाही.

प्रक्रियासमाविष्ट

आपणमाझ्याअभ्यासामध्येस्वत: लानावनोंदणीकरण्याससहमतअसल्यास, आपणयाअभ्यासासाठीपात्रआहातकायहेजाणूनघेण्यासाठीआपलातपशीलवारमागीलइतिहास घेतलाजाईल.

आपल्याकडेबहिष्कारमानदंडांपैकीएकअसेलतरआपल्यालायाअभ्यासातनामांकितकेलेजाणार नाहीकारणआपलीसुरक्षिततताहीप्राथमिकचिंताआहे.

आपणयाअभ्यासातसहभागीहोण्यासाठीपात्रअसालतर,

आपल्यासंमतीघेतल्यानंतरआपल्याला 1

ग्रॅमट्रॅनेक्सॅमिकऍसिडकिंवाप्लेसबोऔषधाचीव्यवस्थाकेलीजाईलजीएकनिष्क्रियऔषधआहेजी

बाळाच्याप्रसाराच्यानंतरत्वरितनसलेल्यामार्गाने 2 मिलीसामान्यलवणआहे.

पोस्टआंशिकरक्ततोटावरीलट्रॅनेक्सॅमिकऍसिडचेपरिणामअभ्यासण्यासाठी.

आपलेरक्तपरीक्षणपोस्टडिलिव्हरीडे 2 वरकेलेजाईल,

ज्यामध्येआपल्यारक्तातीलमापदंडातीलबदलाचेप्रमाणतपासण्यासाठी 2

मिलीरक्तकाढूनटाकावेजेऔषधाच्याफायद्यांचेसंकेतआहेत.

आपल्यालामाहितहोण्याच्यातारखेपर्यंतरक्तदाबनियंत्रितकरण्यासाठीआपल्यालाअतिरिक्तउ पचारपाहिजेअसल्यास. डिस्चार्जकेल्यानंतर, आपण 3 महिन्यांनंतरअनुसरणकरल .

दुष्परिणाम

आधीसांगितल्याप्रमाणेतेथेऔषधे, उलट्या,

थ्रोम्बोसिसयाऔषधांचाकाहीप्रतिकूलप्रभावअसूशकतो.

आपणकोणत्याहीप्रतिकूलप्रभावांचाविकासकेल्यासत्याचाआपल्यासाठीबराचउपयोगकेलाजाई

ल.

अशापरिस्थितीतआम्हीएकत्रचर्चाकरूआणिआपणयाअभ्यासातपुढेचालूठेवूइच्छितअसालयाब

द्दलआपणाससल्लादिलाजाईल .

धोके

यासंशोधनामध्येभागघेतल्यास,

आपणासऔषधांचादुष्परिणामअनुभवेलअशीशक्यताआहे.अशीशक्यतादेखीलआहेकीऔषधक

दाचितकार्यकरूशकतनाहीतसेचआम्हीयाचीअपेक्षाकरीतआहोत.

जरयापैकीकोणतीहीपरिस्थितीउद्भवलीतरआपल्यालाआपल्यारूग्णालयातदेऊकेल्याजाणार्योर

क्तसंक्रमणास रक्तसंक्रमणासनियंत्रितकरण्यासाठीनियमितउपचारदेण्यातयेतील.

फायदे

यासंशोधनामध्येभागघेण्याचेफायदेम्हणजेआपलेसहभागट्रॅनएक्सॅमिकऍसिडअसल्यासआपण

डिलीव्हरीनंतरआपल्याकडेझालेल्यारक्ततोटाचीसंख्याकमीकरण्यातमदतकरेल.

जरीआपल्यालानिष्क्रियकिंवाप्लेसबोऔषधदेण्यातआलातरीहीआपल्यालारक्ततोटासाठीनिरी

क्षणकेलेजाईलआणिआवश्यकअसल्यासयोग्यउपचारदिलेजातील .

पोस्टडिलिव्हरीकालावधीमध्येरक्ततोटाकमीकरण्यासाठीआणिमातृभाषासुधारण्यासाठीसध्या

केलेल्याउपचारांमध्येसुधारणाकरण्यासाठीवैद्यकीयसंशोधनामध्येआपलीसहभागमहत्त्वपूर्ण

आहे .

सहभागासाठीआर्थिकप्रोत्साहनः

नामांकितरुग्णांनाआर्थिकप्रोत्साहनदिलेजातनाही.

हेपूर्णपणेसंशोधनसंकल्पनेसहकेलेजातआहेआणिसवेखचोचीतपासणीकरणायोंकडूनकेलीजाई

ल.

गोपनीयताआणिगुप्तता:

केवळआपणचसंशोधनविषयआहातहेचलोकशोधसंघाचेसदस्यअसतील.

आपल्याबद्दलकोणतीहीमाहितीकिंवासंशोधनदरम्यानआपल्याद्वारेप्रदानकेलेलीमाहितीआप

ल्यालिखितपरवानगीशिवायइतरांनाप्रकटकेलीजाणारनाही.

1. आपल्याअधिकारांचेआणिकल्याणाचेरक्षणकरण्यासाठीआणीबाणीमध्ये.

2. कायद्यानुसारआवश्यकअसल्यास.

परिणामप्रकाशितकरण्यासाठीअधिकृतताः

जेव्हाशोधपरिणामांचेप्रकाशनकिंवाचर्चाकेलीजातेतेव्हाकॉन्फरन्समध्येकोणतीहीमाहितीप्रदर्शि

तकेलीजाणारनाहीजीआपलीओळखउघडकरेल.

याअभ्यासाशीसंबंधितकोणतीहीमाहितीआणिआपल्यासहओळखलीजाऊशकतेतीगोपनीयराही

ल. अभ्यासाच्यानिकालांचामातृपरिणामसुधारण्यासाठीवापरकेलाजाईल.

अभ्यासातूननकारकिंवामागेघेण्याचाअधिकारः

आपणइच्छितनसल्यासआपल्यालायासंशोधनातसहभागीहोण्याचीआवश्यकतानाही.

आपणकोणत्याहीवेळीअभ्यासपासूनमागेघेऊशकता.

पैसेकाढण्यासाठीकोणतीहीदंडहोणारनाही.

याहॉस्पिटलमध्येआपलेउपचारआणिकाळजीघेण्यातआपणसहभागघेण्याससहमतआहातकि

वानाहीयाचीपर्वानकरताबदलहोणारनाही.

आवश्यकअसल्यासअभ्यासमधूनआपणकाढलेजाऊशकत .

पर्यायी:

आपणकोणत्याहीवेळीयाअभ्यासातूनस्वत: लाकाढूनघेण्यासमुक्तआहात.

आपणअभ्यासातभागघेण्यासनकारदिल्यासदेखीलआपणनियमितपणेपोस्टरनेटलकेअरप्राप्त करणेसुरूठेवूशकता. आपणजास्तप्रमाणातपोस्टप्टामरक्तस्त्रावविकसितकेलापाहिजे, तरआपणत्याअभ्यासातूननाकारलेतरीहीआपल्याशीत्वरितत्याचाउपचारकेलाजाईल.

अभ्यासातभागघेण्यासाठीआपल्यानिर्णयावरपरिणामकरणार्याकोणत्याहीनवीनमाहितीबद्दल आपल्यालासूचितकेलेजाईल .

संस्थात्मव / प्रायोजकधोरण:

अभ्यासाशीसंबंधितअसलेल्याकोणत्याहीदुखापतीझाल्यास, काहेर, बेलागवीद्वारेउपचारकेलेजातील.

कायद्याद्वारेअशावैद्यकीयउपचारांसाठीकोणतेहीनुकसानभरपाईकिंवापेमेंटनाही.

जरआपणजखमीझालाअसालतरआपण**REG. NO. BJ0118004**,पोस्टग्रेजुएटविद्यार्थी, ओबस्टेट्रिक्सआणिगायनॉकॉलॉजीविभाग,

काहेरकिंवाफोननं._____वरसंपर्कसाधूशकता .

संपर्कांचीमाहिती:

जरभविष्यातीलकिंवाअभ्याससंबंधितजखमकिंवाआजारांच्याबाबतीतआपणकाहीप्रश्नअस ल्यास, आपणREG. NO. BJ0118004, पोस्टग्रॅज्युएटविद्यार्थी, ओबस्टेट्रिक्सआणिगायनॉकॉलॉजीविभाग, केएलईहॉस्पीटलआणिएमआरसी, फोननं.शीसंपर्कसाधूशकता. _____किंवाडॉ_____.डी. (ओबीजी), प्राध्यापक, ओबस्टेट्रीक्सआणिगायनकोलॉजीविभाग, केएलईएसहॉस्पिटलआणिएमआरसी, काहेरबेलगवी, फोनक्रमांक: _____ .

अभ्यासाच्यारूपातआपल्याअधिकारांबद्दलआपल्यालाकाहीप्रश्नअसतीलतरआपणडॉ.रुपाबेलाड,मेडिकलकॉलेजचेअध्यक्ष, मानवविषयासंशोधनसंस्था, फोननं .83131 2473777 एटी - 1527 जेएनमेडिकलकॉलेजचेचेअरमनम्हणूनअध्यापकम्हणूनसंपर्कसाधूशकता. वैद्यकीयमहाविद्यालय, बेलागवी.

संमतीविधान

मी, _____

याअभ्यासातसहभागीहोण्यासाठीस्वेच्छेनेसहमतआहे.

यासंमतीफॉर्मेवरस्वाक्षरीकरुनमीमाझेकोणतेहीकायदेशीरअधिकारसोडूनदेतनाही.

मीकोणत्याहीवेळीअभ्यासमागेघेऊशकते. मीमाझ्यास्वत:च्यास्थानिकभाषेतीलवाचनकिंवावाचनकेल्यानंतरजोखमीआणिफायदेआणिमाझ्यासर्वप्रश्नांचीउत्तरेघेतल्यानंतरसंमतीफॉर्मेवरस्वाक्षरीकरीतआहे.

सहभागीनाव: _____

सहभागीच्याडाव्याअंगठ्याच्याछाप्याचेस्वाक्षरी: _____

तपासकर्त्याचेनाव: _____ स्वाक्षरी: _____

साक्षीदारांचीनावे: _____ स्वाक्षरी: _____

तारीख : _____

सूचितसहमति

शोधअध्ययनकाशीर्षक:

"योनिडिलिवरीकेबादपोस्टपर्टमहेमोरेजकोरोकनेकेलिएइंजेक्शनट्रनेक्सैमिकएसिड:

एकवर्षअस्पतालआधारितयादृच्छिक, प्लेसबो-नियंत्रितपरीक्षण"

मुख्यजॉचकर्ता: -

REG. NO. BJ0118004

स्नातकोत्तर

प्रसूतिविज्ञानऔरस्त्रीरोगविज्ञानविभाग,

जेएनमेडिकलकॉलेज, बेलगावी

सह-अन्वेषक

डॉ_____

प्रोफेसर,

प्रसूतिविज्ञानऔरस्त्रीरोगविज्ञानविभाग,

जेएनमेडिकलकॉलेज, बेलगावी

अनुसंधानअध्ययनमेंभागीदारीकेलिएसहमति

श्रीमती_____हमआपकोयोनिडिलीवरीकेबादपोस्टपर्टमहेमोरेजकोरोकनेकेलिएइंजेक्शनट्रेनेक्सैमिकएसिडनामकअध्ययनमेंखुदकोनामांकितकरनेकाअनुरोधकररहेहैं:एमएसमेंपोस्टग्रेजुएटडॉ.**REG. NO. BJ0118004**द्वाराआयोजितएकवर्षअस्पतालआधारितयादृच्छिक, प्लेसबो-नियंत्रितपरीक्षण "डॉ._____लप्रोफेसर,ओबस्टेट्रिक्सएंडगायनकोलॉजीविभाग, जेएनमेडिकलकॉलेज, काहेरबेलगावीकेमार्गदर्शनमें.

शोधअध्ययनकाउद्देश्यट्रेनेक्सैमिकएसिडकेफायदेमंदप्रभावऔरपोस्टआंशिकरक्तहानिकीमात्राकोकमकरनेकीइसकीक्षमताकोजाननाहै।मैंअपनेअध्ययनकेलिएजांचकर्ताबनूंगा।इसअध्ययनकोवित्तपोषितनहींकियाजारहाहै।मैंआपकोइसशोधपरियोजनाकेबारेमेंजानकारीदेनेजारहाहूं।निर्णयलेनेसेपहले,

आपअनुसंधानकेबारेमेंसहजमहसूसकरनेवालेकिसीभीव्यक्तिसेबातकरसकतेहैं।

अध्ययनकाउद्दे :

सामान्यवितरणकेबादरक्तस्रावहमारेदेशमेंसबसेगंभीरमातृजटिलताहै।यद्यपिरक्तहानिकोनियंत्रितकरनेकेलिएविभिन्नदवाएंहैं,

लेकिनसामान्यवितरणकेबादरक्तहानिकीमात्राकोकमकरनेकेलिएनिवारकप्रबंधनकीआवश्यकताहै।यहअनियंत्रितरक्तहानिकोरोकनेकेलिएशल्यचिकित्साप्रक्रियाओंकीआवश्यकताकोभीकमकरदेगा।यहअध्ययनसामान्यवितरणकेबादरक्तहानिकीमात्राकोकमकरनेमेंइंजेक्शनट्रेनेक्सैमिकएसिडकेप्रोफाइलैक्टिकउपयोगकेप्रभावकोजाननेमेंहमारीसहायताकरेगा।

अध्ययनकाप्रक

यहअध्ययनएकहस्तक्षेपअध्ययनहै।इसमेंइंजेक्शनट्रेनेक्सैमिकएसिडयासामान्यलवणकोइंट्रावेनसरूटद्वारातुरंतवितरणऔररक्तहानिकेमापकेसाथ-

साथतीसरेमहीनेकेपोस्टडिलीवरीतकअनुवर्तीयात्राओंकेप्रशासनकाप्रशासनशामिलहै।

प्रतिभागीचयन

हमसभीअध्ययनगर्भवतीमहिलाओंकोआमंत्रितकररहेहैंजोइसअध्ययनमेंभागलेनेकेलिएहमारे अस्पतालजातेहैं।

स्वैच्छिकभागीदारी

शोधमेंआपकीभागीदारीस्वैच्छिकहै।यहआपकीपसंदहैकिभागलेनाहैयानहीं।आपकानिर्णयहैकि अध्ययनमेंभागलेनाहैयानहीं,
आपकोवर्तमानयाभविष्यकीस्वास्थ्यदेखभालसेवाओंकोनहींबदलेगाऔरजेएनकेसाथआपकेरि श्तेकोप्रभावितनहींकरेगा।चिकित्सामहाविद्यालय।यदिआपइसअध्ययनमेंभागलेनेकाविकल्प नहींचुनतेहैं,
तोभीआपकोहमारेअस्पतालमेंदीगईपोस्टडिलीवरीरक्तहानिकोनियंत्रितकरनेकेलिएनियमितउ पचारकीपेशकशकीजाएगी।यदिआपइसअध्ययनमेंभागलेनेसेइनकारकरतेहैंतोभीआपकोहमारे अस्पतालमेंनियमितरूपसेप्रसवोत्तरदेखभालप्राप्तकरनाजारीरहेगा।यदिआपभागलेनेकाफैस लाकरतेहैंतोआपकिसीभीसमयवापसलेनेकेलिएस्वतंत्रहैं।

दवापरजानकारी

इसअध्ययनमेंहमजिसदवाकापरीक्षणकररहेहैंवहइंजेक्शनट्रेनेक्सैमिकएसिडहैजिसेपहलेडिलीव रीकेबादअत्यधिकरक्तहानिकेइलाजकेलिएइस्तेमालकियागयाथा।दवाकोसनफार्मालेबोरेटरीज सेआपूर्तिकीजाएगी।वितरणकेबादरक्तहानिकोकमकरनेकेलिए,
हमइसअध्ययनमेंनिवारकउपायकेरूपमेंइसकाउपयोगकररहेहैं।आपकोपताहोनाचाहिएकिइसद वामेंमतली, उल्टी,
थ्रोम्बिसिसजैसेकुछसाइडइफेक्ट्सहैं।आपकिसीभीसाइडइफेक्ट्सकीजांचकेलिएपहले 2 घंटोंकेलिएहर 15 मिनटकीनिगरानीकरेंगे, आपकोकिसीभीकोदेखनेकेलिए 3 महीनेकेबादडिलीवरीकापालनकियाजाएगादुष्प्रभावऔरउचितउपचारइसकेलिएदियाजाएगा.

इसशोधमेंकुछप्रतिभागियोंकोसामान्यलवणदियाजाएगाजोएकनिष्क्रियदवाहैजिसेप्लेसबोदवा केरूपमेंभीजानाजाताहैताकिपोस्टपार्टमरक्तहानिकोनियंत्रितकरनेमेंट्रेनेक्सैमिकएसिडकेप्रभाव कीतुलनाकीजासके।पोस्टडिलीवरीब्लूज़लॉसकोनियंत्रितकरनेमेंएकनिष्क्रियदवायाप्लेसबोदवा

काकोईप्रभावनहींपड़ताहै।ट्रैनएक्सैमिकएसिडकेफायदेमंदप्रभावकोजाननेकेलिएइसकाउपयोग केवलइसअध्ययनमेंकियाजारहाहै।सामान्यखाराप्रशासनकेसाथकोईजोखिमनहींहै.

प्रक्रियाशामिल :

यदिआपअपनेअध्ययनमेंखुदकोनामांकितकरनेकेलिएसहमतहैं,

तोयहजाननेकेलिएआपकाविस्तृतइतिहासइतिहासलियाजाएगाकिक्याआपइसअध्ययनकेलिए योग्यहैंयानहीं।यदिआपकेपासबहिष्करणमानदंडोंमेंसेएकभीहै,

तोआपइसअध्ययनमेंनामांकितनहींहोंगेक्योंकिआपकीसुरक्षाप्राथमिकचिंताहै।यदिआपइसअ ध्ययनमेंभागलेनेकेपात्र , तोआपकीसहमतिलेनेकेबादआपकोएकदवायातो 1

ग्रामट्रेनेक्सैमिकएसिडयाप्लेसबोप्रशासितकियाजाएगाजोएकनिष्क्रियदवाहैजोबच्चेकेवितरण केतुरंतबादअंतःशिरामार्गद्वारा 2 मिलीलीटरसामान्यनमकीनहोतीहै,

पोस्टआंशिकरक्तहानिपर tranexamic

एसिडकेप्रभावकाअध्ययनकरनेकेलिए।आपकारक्तपरीक्षणपोस्टडिलीवरीदिन 2

परकियाजाएगा, जिसमेंआपकेरक्तकेपैरामीटरमेंबदलावकीजांचकरनेकेलिए 2

मिलीलीटररक्तवापसलेनाशामिलहैजोकिइस्तेमालकीजानेवालीदवाकेलाभोंकासंकेतहै।आपको पतालगानेकेलिएनिर्वहनकेदिनतकपालनकियाजाएगाअगरआपकोरक्तहानिकोनियंत्रितकरने केलिएकोईअतिरिक्तउपचारकीआवश्यकताहै।निर्वहनकेबाद, आपको 3

महीनेतककापालनकियाजाएगा।

दुष्प्रभाव

जैसाकिपहलेसेहीबतायागयाहैकिइसदवाकेकुछप्रतिकूलप्रभावजैसेमतली, उल्टी,

थ्रोम्बिसिसहोसकतेहैं।यदिआपकिसीभीप्रतिकूलप्रभावकोविकसितकरतेहैंतोआपसेइसकाइलाज कियाजाएगा।ऐसेपरिदृश्यमेंहमएकसाथचर्चाकरेंगेऔरइसबारेमेंआपसेपरामर्शकियाजाएगाकि क्याआपइसअध्ययनमेंजारीरखनाचाहतेहैं।

जोखिम

इसशोधमेंभागलेनेसे,

संभावनाहैकिआपकोदवाकेप्रतिकूलप्रभावकाअनुभवहोगा।एकसंभावनाभीहैकिदवाकामनहींकर सकतीहैऔरसाथहीहमइसकीउम्मीदकररहेहैं।अगरइनमेंसेकोईभीस्थितिउत्पन्नहोतीहै,

तोआपकोप्रसवकेबादरक्तहानिकोनियंत्रितकरनेकेलिएहमारेअस्पतालमेंनियमितउपचारदिया जाएगा.

लाभ

इसशोधमेंभागलेनेकेलाभयहहैकिआपकीभागीदारीडिलीवरीकेबादआपकेपासहोनेवालीरक्तहा निकीमात्राकोकमकरनेमेंमददकरेगीयदिआपकोट्रनेक्सैमिकएसिडप्रशासितकियाजाताहै।भलेही आपकोनिष्क्रिययाप्लेसबोदवादीजातीहै,

फिरभीआपकोरक्तहानिकेलिएनिगरानीकीजाएगीऔरयदिआवश्यकहोतोउचितउपचारदियाजा एगा.

पोस्टवितरणअवधिमेंरक्तहानिकोकमकरनेऔरमातृस्वास्थ्यमेंसुधारकरनेकेलिएवर्तमानमेंइ लाजमेंसुधारकेलिएचिकित्साअनुसंधानमेंआपकीभागीदारीमेंमहत्वपूर्णयोगदानहै.

भागीदारीकेलिएवित्तीयप्रोत्साहन

नामांकितमरीजोंकोकोईवित्तीयप्रोत्साहननहींदियाजारहाहै।यहपूरीतरहसेशोधकेविचारसेकिया जारहाहैऔरअध्ययनकीसभीलागतजांचकर्तादवारालीजाएगी।

गोपनीयताऔरगोपनीयता :

एकमात्रलोगजोजानतेहोंगेकिआपशोधविषयहैं,

वेशोधदलकेसदस्यहोंगे।शोधकेदौरानआपकेद्वाराप्रदानकीगईजानकारीयाजानकारीकेबारेमेंको ईजानकारीआपकेलिखितअनुमतिकेबिनादूसरोंकोप्रकटनहींकीजाएगी: 1.

अपनेअधिकारोंऔरकल्याणकीरक्षाकेलिएआपातकालमें। 2. यदिकानूनद्वाराआवश्यव .

परिणामप्रकाशितकरनेकेलिएप्राधिकरण

जबशोधकेपरिणामप्रकाशितहोतेहैंयाचर्चाकरतेहैं,एकसम्मेलनमें,

कोईजानकारीप्रदर्शितनहींकीजाएगीजोआपकीपहचानकाखुलासाकरेगी।इसअध्ययनकेसंबंधमें प्राप्तकीगईकोईभीजानकारीऔरआपकेसाथपहचानाजासकताहैगोपनीयरहेगा।अध्ययनकेनती जेमातृपरिणाममेंसुधारकेलिएइस्तेमालकिएजाएंगे।

अध्ययनसेइनकारकरनेयावापसलेनेकाअधिका :

यदिआपचाहेंतोआपकोइसशोधमेंभागलेनेकीज़रूरतनहींहै।आपअध्ययनसेकिसीभीसमयवापस लेसकतेहैं।वापसीकेलिएकोईदंडनहींहोगा।इसअस्पतालमेंआपकाउपचारऔरदेखभालइसबातके

बावजूदनहींबदलेगीकिआपभागलेनेकेलिएसहमतहैंयानहीं।यदिआवश्यकहोतोआपकोअध्ययन सेनिकालदियाजासकताहै.

वैकल्पिक:

आपकिसीभीसमयइसअध्ययनसेखुदकोवापसलेनेकेलिएस्वतंत्रहैं।यदिआपअध्ययनमेंभागलेने सेइनकारकरतेहैंतोभीआपकोनियमितपोस्टप्रसवदेखभालजारीरहेगी।यदिआपअत्यधिकपोस्ट पटेमरक्तस्रावविकसितकरनाचाहतेहैंतोआपकोतुरंतइसकेलिएइलाजकियाजाएगाभलेहीआपने अध्ययनसेइनकारकरदियाहो।आपकोकिसीभीनईजानकारीकेबारेमेंसूचितकियाजाएगाजोअध्य यनमेंभागलेनेकेआपकेफैसलेकोप्रभावितकरसकताहै।

संस्थागत / प्रायोजककीनीति:

अध्ययनसेसंबंधितकिसीभीचोटकीस्थितिमें,काहेर,

बेलगावीकेमाध्यमसेउपचारउपलब्धकरायाजाएगा।कानूनद्वाराइसतरहकेचिकित्साउपचारके लिएकोईमुआवजायाभुगताननहींहै।यदिआपघायलहोगएहैंतोआपREG. NO. BJ0118004, पोस्टग्रेजुएटछात्र, प्रसूतिऔरस्त्रीरोग विभाग, ,काहेरयाफोननंबरसेसंपर्ककरसकतेहैं: _____

संपर्कविवरण:

यदिआपकेपासअध्ययनसेसंबंधितकोई श्नहैं, भविष्यमेंयाअध्ययनसेसंबंधितचोटयाबीमारीकेमामलेमें,आपREG. NO. BJ0118004, पोस्टग्रेजुएटछात्र, ओबस्टेट्रिक्सऔरगायनकोलॉजीविभाग , केएलईअस्पतालऔरएमआरसी, फोननंबरसेसंपर्ककरसकतेहैं: _____याडॉ _____ (ओबीजी), प्रोफेसर,ओब्स्टेट्रिक्सएंडगायनकोलॉजीविभाग, केएलईएसअस्पतालऔरएमआरसी, काहेरबेलगावी, फोननंबर: _____

यदिअध्ययनअध्ययनकेरूपमेंआपकेअधिकारोंकेबारेमेंआपकेकोईप्रश्नहैं, तोआपमानवविषयअनुसंधानपरजेएनमेडिकलकॉलेजइंस्टीट्यूशनलएथिक्सकमेटीकेअध्यक्ष केरूपमेंबालचिकित्साकेप्रोफेसरडॉरूपाएमबेलादसेसंपर्ककरसकतेहैं, फोननंबर 0831 2473777 एक्सटी -1527 जेएनमेंमेडिकलकॉलेज, बेलगावी।

सहमतिपत्र

मैं, _____

स्वेच्छासेइसअध्ययनमेंभागलेनेकेलिएसहमतहूं।इससहमतिफॉर्मपरहस्ताक्षरकरकेमैंअपनेकिसीभीकानूनीअधिकारकोनहींछोड़रहाहूं,

मैंकिसीभीसमयअध्ययनसेवापसआसकताहूं।मैंअपनेस्वयंकेस्थानीयभाषामेंपढ़नेयापढ़नेकेबादसहमतिफॉर्मपरहस्ताक्षरकररहाहूं,

जिसमेंजोखिमऔरलाभशामिलहैंऔरमेरेसभीसवालोंकेजवाबदिएगएहैं।

भागलेनेवालेकानाम : _____

बाएंअंगूठेकाहस्ताक्षरप्रतिभागीकाप्रिंट: _____

जांचकर्ताकानाम: _____ हस्ताक्ष : _____

साक्षीकानाम: _____ हस्ताक्ष : _____

तारीख_____

ANNEXURE III - SCREENING FORM

Screening | | | | | | number:

Date of screening (dd-mm-yyyy) _____

First name: _____

Middle name: _____

Last name: _____

Husband's name: _____

Age (years): _____

IP number: _____

Address: H.no-_____

Street-_____

Taluka-_____

District-_____

Phone | | | | | | | | | | number

Phone | | | | | | | | | | number

Landline(optional)-

Registered	
Unregistered	

Exclusion criteria	YES	NO
▪ History of thrombosis		
o venous-deep vein thrombosis	☐	☐
o pulmonary embolism	☐	☐
o arterial -angina pectoris	☐	☐
o myocardial infarction	☐	☐
o stroke	☐	☐
o compliants of chest pain	☐	☐
▪ History of epilepsy or seizure	☐	☐
▪ Any known case of		
➢ cardiovascular	☐	☐
➢ renal	☐	☐
➢ liver disorders	☐	☐
▪ Autoimmune disease	☐	☐
▪ Severe hemorrhagic disease	☐	☐

- Placental Abnormalilty-
  - Placenta previa ☐ ☐
  - Invasive placenta ☐ ☐
  - Abruptio placentae ☐ ☐
- Eclampsia ☐ ☐
- HELLP syndrome ☐ ☐
- Intra utero fetal death ☐ ☐
- Administration of during the week before delivery
  - low-molecular-weight heparin ☐ ☐
  - antiplatelet agents ☐ ☐

1) previous caesarean section ☐ ☐
2) consent ☐ ☐

ANNEXURE IV - PROFORMA

PROFORMA

"Injection Tranexamic Acid for Preventing Postpartum Hemorrhage after Vaginal Delivery: one year hospital based randomized, placebo-controlled trial".

First Name Middle Name Last name

Name -

Age- rs

Address- House Number-

Street Taluk District

Phone number 1-

Date of admission-

Date of discharge-

IP No.-

Date of enrolment-

Randomization No.

Group -

Obstetric history:

Gravida Para Living Abortion

Menstrual history:

LMP			
EDD			
CEDD			
POG			

General physical examination:

Pulse rate	**/minute**	
Blood pressure	**mmHg**	
	Yes	No
Pallor		
Icterus		
Pedal oedema		
Body mass index		
-Weight(Kg)		
- Height (m)		

Systemic examination:

Size of uterus	
Presentation	
Fetal heart sounds	/minute
Per vaginal examination	Dilatation ☐ Length ☐ Station ☐ Position ☐ Consistency ☐

Investigations:

Date	
Hemoglobin	g%
Peripheral smear	
Platelets	/cumm
Packed cell volume((PCV)	

Delivery and baby details

Date- ☐☐ ☐☐ ☐☐☐☐

Time- ☐☐ **gender** ☐ **weight** ☐

POST PARTUM BLOOD LOSS

Blood loss in millilitres(ml)	Group 1- tranexamic acid administered	Group 2- Placebo administered
Blood loss at the end of 30 minutes	Ml	ml
Blood loss at the end of 2 hours	Ml	ml
Mean total blood loss	ml	ml

Use of additional uterotonics	Group 1- tranexamic acid administered	Group 2- Placebo administered
Injection Methergin	Dose Route	Dose Route
Injection carboprost	Dose Route	Dose Route
T Misoprostal	Dose Route	Dose Route
Others		

If blood transfusion done, details regarding transfusion

Postnatal day of transfusion ☐☐

PCV ☐ FFP ☐ P ☐ SDP ☐ ☐

Need for blood transfusion	Group 1- tranexamic acid administered	Group 2- Placebo administered
Blood transfusion up to date of discharge		

Additonal surgical procedures	Group 1- tranexamic acid administered	Group 2- Placebo administered
Uterine artery embolization		
Emergency hysterectomy		
Others		

Laboratory parameters	Group 1- tranexamic acid administered	Group 2- Placebo administered
1)Hemoglobin	gram %	gram %
• Antenatal period		
• Post natal day 2		
• Mean value		
2) PCV		
• Antenatal period		
• Post natal day 2		
• Mean value		

Number of days of hospital stay | | |

Hemodynamic parameters	Group 1- tranexamic acid administered	Group 2- Placebo administered
1) Pulse rate	beats/minute	beats/minute
• At 15 minutes		
• At 30 minutes		
• At 45 minutes		
• At 1 hour		
• At 2 hours		
2) Blood pressure	mmHg	mmHg
• At 15 minutes		
• At 30 minutes		
• At 45 minutes		
• At 1 hour		
• At 2 hours		

Adverse effects

Mild adverse symptoms	Group 1- tranexamic acid administered	Group 2- Placebo administered
• Nausea		
• Vomiting		
• Dizziness		

Severe adverse symptoms upto 3 months	Group 1- tranexamic acid administered	Group 2- Placebo administered
• Deep vein thrombosis		
• Pulmonary embolism		
• MI		
• Seizures		
• Renal failure		

	INCIDENCE OF ATONIC PPH	INCIDENCE OF TRAUMATIC PPH	INCIDENCE ATONIC PPH + TRAUMATIC PPH
TXA GROUP			
PLACEBO GROUP			

ANNEXURE V - KEY TO MASTERCHART

Sl.No.	–	serial number
IP No.	–	In Patient number
BMI	-	Body mass Index
PPH	-	Postpartum hemorrhage
SBP	-	Systolic Blood Pressure
DBP	-	Diastolic Blood Pressure
Hb	-	Hemoglobin
PCV	-	Packed Cell Volume

TXA GROUP

														type of PPH			pre delivery			post delivery			aboratory paramete		Adverse effects										
sl no	date of admission	regsitered/ Unregistered	IP no.	age	Gravida	gravidity	BMI (kg/m2)	mean blood loss (ml)						Atonic PPH	Truamtic PPH	atonic +truamtic	pulse	SBP	DBP	pulse	SBP	DBP	mean change in Hb	Mean change PCV	nausea	vomiting	dizziness	nausea + vomiting	vomiting +dizzines	nausea + dizziness	Blood transfusion	additonal uterotonics yes or no	Hospital stay - </= 3 days or > 3 days
								<100	100-150	151-200	201-300	300-500	>500				beats /minute	mm Hg	mmHg	beats /minute	mm Hg	mm Hg											
1	1/20/2019	registred	923572	21	primigravida	1st	normal			200				No	No	No	88	110	70	90	110	70	0.5	-0.2	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
2	1/28/2019	unregistered	924536	28	multigravida	2nd	normal			180				No	No	No	84	116	74	76	120	80	0.6	3.9	absent	absent	absent	absent	absent	absent	no	no	>3 days
3	1/30/2019	unregistered	925620	21	primigravida	1st	normal			170				No	No	No	88	100	78	70	130	70	1.1	5.5	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
4	3/1/2019	unregistered	930905	25	multigravida	5th	pre obesity				230			No	No	No	76	102	76	90	100	60	2.1	8.7	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
5	3/5/2019	unregistered	931670	29	multigravida	3rd	normal		150					No	No	No	76	116	74	84	120	80	-0.1	-2.6	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
6	3/6/2019	registred	932087	22	multigravida	3rd	normal				230			No	No	No	88	116	88	86	110	70	1.1	-0.07	present	absent	absent	absent	absent	absent	no	no	</= 3 days
7	3/7/2019	unregistered	932531	28	primigravida	1st	normal		150					No	No	No	78	100	86	80	120	70	1.4	2.1	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
8	3/8/2019	unregistered	932717	24	primigravida	1st	pre obesity				220			No	No	No	76	102	78	76	110	70	1.7	3.2	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
9	3/9/2019	unregistered	932914	25	multigravida	2nd	normal				250			No	No	No	90	106	74	80	110	70	1.7	1.3	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
10	3/14/2019	unregistered	933999	21	primigravida	1st	normal		150					No	No	No	76	116	74	70	110	70	2.8	8.6	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
11	3/16/2019	unregistered	934321	23	primigravida	1st	normal					300		No	No	No	74	100	86	98	116	76	1	3.3	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
12	3/29/2019	registred	936740	19	primigravida	1st	normal	100						No	No	No	88	102	76	102	110	70	0.5	7.5	present	absent	absent	absent	absent	absent	no	no	</= 3 days
13	4/6/2019	unregistered	938326	21	primigravida	1st	normal			200				No	No	No	88	118	74	88	110	70	1.1	0.9	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
14	4/16/2019	unregistered	940434	26	multigravida	2nd	normal			200				No	No	No	86	108	78	90	110	70	2	4.5	absent	present	absent	absent	absent	absent	no	no	</= 3 days
15	5/1/2019	registred	943183	28	multigravida	2nd	normal			200				No	No	No	88	100	60	90	120	70	0.4	-1	present	absent	absent	absent	absent	absent	no	no	</= 3 days
16	5/3/2019	unregistered	943734	25	multigravida	2nd	normal					450		No	No	No	74	108	76	120	100	60	1.1	5.8	absent	absent	absent	present	absent	absent	no	no	</= 3 days
17	5/14/2019	unregistered	945925	27	primigravida	1st	normal					330		No	No	No	76	116	74	64	120	70	1.6	3.6	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
18	5/14/2019	registred	945833	23	multigravida	2nd	normal	100						No	No	No	88	116	72	60	100	70	1.9	6.4	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
19	5/16/2019	unregistered	946275	26	multigravida	4th	normal						650	yes	No	No	76	118	70	110	110	70	1.2	6	absent	present	absent	absent	absent	absent	no	yes	</= 3 days
20	5/16/2019	unregistered	946435	28	primigravida	1st	normal			200				no	No	No	78	118	70	90	100	70	1.6	6.8	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
21	5/20/2019	unregistered	947155	24	primigravida	1st	normal					300		no	No	No	78	108	80	88	120	70	1.6	2.7	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
22	5/21/2019	unregistered	947428	30	multigravida	3rd	<18.5					300		no	No	No	82	116	74	90	130	90	0	-1.25	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
23	5/22/2019	unregistered	947471	28	multigravida	2nd	normal		150					no	No	No	84	108	76	90	120	70	0.5	1	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
24	5/24/2019	unregistered	948040	24	multigravida	2nd	normal				250			no	No	No	88	118	68	94	110	70	0.9	1	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
25	6/1/2019	unregistered	949601	20	multigravida	2nd	normal					350		no	No	No	70	116	78	88	128	82	1.9	3.1	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
26	6/2/2019	registred	949673	21	primigravida	1st	normal					400		no	No	No	88	108	82	78	116	74	3.8	11	absent	absent	absent	absent	absent	absent	yes	no	>3 days
27	6/3/2019	unregistered	949936	22	primigravida	1st	normal	150						no	No	No	81	116	74	70	100	70	2.2	6.1	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
28	6/4/2019	unregistered	949965	23	multigravida	2nd	normal					350		no	No	No	82	118	70	66	116	80	1.2	0.4	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
29	6/3/2019	registred	949930	25	multigravida	2nd	normal			200				no	No	No	88	108	76	68	110	76	0.8	1.1	absent	absent	absent	absent	absent	absent	no	no	>3 days
30	6/4/2019	unregistered	950115	22	multigravida	2nd	normal		150					no	No	No	84	110	74	76	120	80	0.8	1.3	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
31	6/5/2019	registred	sumitra ya	24	multigravida	4th	normal						650	no	yes	No	86	118	80	80	126	84	4	8	absent	absent	absent	absent	absent	absent	yes	no	</= 3 days
32	6/6/2019	unregistered	950298	21	primigravida	1st	normal			200				no	No	No	82	108	66	86	126	82	1.5	2.8	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
33	6/15/2019	registred	952229	19	primigravida	1st	normal					400		no	No	No	82	110	80	80	110	74	3.8	15	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
34	6/19/2019	registred	952884	32	multigravida	3rd	normal			200				no	No	No	86	116	78	74	118	90	1.6	0.7	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
35	6/24/2019	registred	954026	21	primigravida	1st	pre- obesity			200				no	No	No	78	118	78	80	116	74	1.3	2.7	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
36	6/28/2019	registred	954852	31	primigravida	1st	normal					450		no	No	No	88	108	70	74	120	76	3.2	6.9	absent	absent	absent	absent	absent	absent	no	no	>3 days
37	6/30/2019	unregistered	955237	19	primigravida	1st	normal			200				no	No	No	74	116	74	72	110	74	2.9	4.5	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
38	6/30/2019	registred	955201	19	primigravida	1st	normal		120					no	No	No	68	136	78	76	118	70	3.2	10.2	absent	present	absent	absent	absent	absent	no	no	</= 3 days
39	7/3/2019	unregistered	955715	22	primigravida	1st	pre- obesity			250				no	No	No	72	132	74	74	116	76	0.9	4.2	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
40	7/9/2019	registred	956872	22	primigravida	1st	pre- obesity			250				no	No	No	80	118	76	82	110	74	1.9	4	absent	absent	absent	absent	absent	absent	no	yes	>3 days
41	7/8/2019	registred	956860	28	multigravida	2nd	normal				300			no	No	No	82	128	70	84	120	70	1.7	5.1	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
42	7/15/2019	registred	958004	22	multigravida	2nd	pre- obesity				300			no	No	No	78	128	84	78	110	80	1.2	2	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
43	7/17/2019	registred	958500	21	primigravida	1st	normal					400		no	No	No	80	110	78	88	110	72	1.2	2.2	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
44	7/15/2019	registred	958143	24	multigravida	2nd	pre- obesity				350			no	No	No	82	108	74	86	118	70	2.1	5.6	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
45	7/19/2019	registred	958973	20	primigravid	1st	class 1			250				no	No	No	78	110	78	88	108	70	0.4	0.2	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
46	7/23/2019	registred	959690	30	multigravida	3rd	normal		200					no	No	No	88	132	82	78	110	74	1.2	1.4	absent	absent	absent	absent	absent	absent	no	no	</= 3 days

49	8/8/2019	unregistered	962856	25	multigravida	2nd	class 1		150					no	No	No	86	110	76	74	116	76	0	0	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
50	8/15/2019	unregistered	964081	24	multigravida	3rd	class 1		200					no	No	No	84	116	74	80	108	70	0	0	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
51	8/16/2019	registred	964413	29	multigravida	2nd	normal			250				no	No	No	88	116	78	86	116	74	0.7	0	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
52	8/17/2019	unregistered	964537	25	multigravida	3rd	class 1		150					no	No	No	78	100	70	84	120	70	0.2	0	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
53	8/19/2019	registred	964854	23	primigravida	1st	class 1			200				no	No	No	80	106	88	76	120	82	2.3	6.6	absent	absent	absent	absent	absent	absent	no	no	>3 days
54	8/28/2019	unregistered	967042	24	multigravida	3rd	normal			200				no	No	No	78	100	70	84	120	80	1.1	0.4	absent	present	absent	absent	absent	absent	no	no	</= 3 days
55	9/9/2019	registred	969565	28	multigravida	4th	normal			200				no	No	No	78	116	72	74	120	70	1.3	2.3	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
56	9/12/2019	registred	970396	26	multigravida	3rd	normal			200				no	No	No	76	104	70	80	118	82	0.5	1.1	absent	absent	absent	absent	absent	absent	no	yes	>/=3 days
57	9/13/2019	registred	970692	21	primigravida	1st	normal			200				no	No	No	88	100	76	86	108	70	0.5	0.6	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
58	9/14/2019	registred	970866	24	multigravida	2nd	normal		150					no	No	No	84	100	70	80	100	78	0.3	2.7	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
59	9/20/2019	registred	972277	25	multigravida	3rd	normal					400		no	No	No	78	100	76	90	112	74	0.8	0	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
60	9/24/2019	registred	973178	24	multigravida	2nd	<18.5						1000	yes	No	No	76	100	70	90	110	70	2.3	3.7	absent	absent	absent	absent	absent	absent	yes	no	>3 days
61	9/30/2019	unregistered	974362	22	multigravida	2nd	pre- obesity			200				no	No	No	74	106	80	76	120	70	0	0	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
62	10/3/2019	unregistered	974994	30	multigravida	2nd	normal	100						no	No	No	68	108	88	78	120	74	0	0.5	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
63	10/4/2019	unregistered	975077	19	primigravida	1st	normal		200					no	No	No	70	116	80	82	110	60	0.2	0.2	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
64	10/6/2019	registred	975446	23	multigravida	2nd	normal			300				no	No	No	78	100	78	86	120	76	0	0	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
65	10/8/2019	unregistered	975727	26	primigravida	1st	class 1				300			no	No	No	76	108	66	80	110	74	2.1	2	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
66	10/7/2019	registred	975623	24	primigravida	1st	normal			250				no	No	No	80	100	60	76	116	70	1.8	2.9	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
67	10/9/2019	unregistered	976089	22	multigravida	3rd	pre- obesity				300			no	No	No	88	118	78	72	110	70	0	0	absent	absent	absent	present	absent	absent	no	no	>3 days
68	10/10/2019	unregistered	976331	22	primigravida	1st	class 1				300			no	No	No	82	120	86	78	110	76	2.5	9	present	absent	absent	absent	absent	absent	no	no	</= 3 days
69	10/13/2019	unregistered	976843	25	primigravida	1st	<18.5		150					no	No	No	86	128	78	88	100	70	0.4	2.2	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
70	10/17/2019	registred	977867	27	multigravida	2nd	normal		200					no	No	No	86	138	78	82	128	76	0	0	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
71	10/17/2019	unregistered	977950	22	primigravida	1st	normal		200					no	No	No	86	128	78	84	110	70	1.6	3.6	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
72	10/17/2019	unregistered	977949	22	primigravida	1st	normal					400		no	No	No	84	120	76	84	120	76	4.3	10.4	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
73	10/17/2019	registred	978851	20	multigravida	2nd	class 1				300			no	No	No	86	108	80	88	110	66	0.6	2.6	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
74	10/24/2019	registred	979285	25	multigravida	2nd	pre- obesity			280				no	No	No	78	108	88	76	126	74	1.9	8.8	absent	absent	absent	absent	absent	absent	no	yes	>3 days
75	10/23/2019	registred	979120	26	primigravida	1st	class 1				300			no	No	No	78	100	78	77	110	70	1	6	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
76	10/25/2019	registred	979567	20	primigravida	1st	normal		200					no	No	No	86	100	78	64	110	76	1	5.1	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
77	10/31/2019	registred	980329	22	primigravida	1st	pre- obesity	100						no	No	No	70	118	70	90	100	78	1.8	9.1	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
78	10/30/2019	unregistered	980216	23	multigravida	2nd	normal					400		no	No	No	70	100	78	78	126	74	3.1	7	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
79	10/31/2019	registred	980449	20	primigravida	1st	normal		150					no	No	No	88	126	84	72	116	74	2.1	4.8	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
80	11/3/2019	registred	980899	25	primigravida	1st	normal		150					no	No	No	78	100	78	84	100	76	1.7	1.1	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
81	11/3/2019	registred	980947	21	primigravida	1st	pre- obesity		150					no	No	No	80	100	76	84	120	76	0.6	1.8	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
82	11/3/2019	registred	981250	29	multigravida	2nd	<18.5			200				no	No	No	82	120	76	82	110	78	1.7	3.6	absent	absent	absent	absent	absent	absent	no	no	>3 days
83	11/4/4019	registered	981602	25	multigravida	2nd	pre- obesity				250			no	No	No	88	116	88	90	120	70	0	0.7	present	absent	absent	absent	absent	absent	no	no	</= 3 days
84	11/6/2019	registred	982150	28	multigravida	2nd	normal		150					no	No	No	80	110	78	80	120	70	0.7	1.1	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
85	11/8/2019	registred	982255	21	multigravida	2nd	pre- obesity		150					no	No	No	72	100	86	82	110	78	1.6	4.2	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
86	11/8/2019	registred	982343	37	multigravida	3rd	class 1			200				no	No	No	76	116	78	84	110	80	1	1.5	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
87	11/9/2019	registred	982526	23	primigravida	1st	pre- obesity			200				no	No	No	76	116	68	88	110	70	2.1	6.8	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
88	11/10/2019	registred	982759	28	primigravida	1st	normal						550	yes	No	No	78	132	68	88	100	66	2.4	5,2	absent	absent	present	absent	absent	absent	no	no	</= 3 days
89	11/11/2019	registred	983787	26	multigravida	3rd	pre- obesity	100						no	No	No	82	110	74	88	100	82	1.1	3.1	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
90	11/15/2019	registred	983814	26	multigravida	2nd	pre- obesity		150					no	No	No	80	108	68	98	118	80	1.3	4.3	absent	absent	absent	absent	absent	absent	no	no	>3 days
91	11/16/2019	unregistered	984019	21	multigravida	2nd	normal			200				no	No	No	76	108	68	86	110	70	3.2	8.2	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
92	11/15/2019	registred	983718	22	primigravida	1st	pre- obesity	100						no	No	No	80	130	78	80	110	70	1	0	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
93	11/18/2019	unregistered	984183	25	multigravida	3rd	normal		150					no	No	No	78	118	78	86	110	70	1.3	4.1	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
94	11/18/2019	unregistered	984208	23	primigravida	1st	pre- obesity			300				no	No	No	78	128	84	78	110	80	2.1	3.2	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
95	11/20/2019	registred	984693	26	multigravida	3rd	pre- obesity		200					no	No	No	82	126	70	86	110	70	0.2	2	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
96	11/21/2019	registred	984947	30	multigravida	2nd	class 1				350			no	No	No	80	136	80	86	110	80	3.8	5.3	absent	absent	absent	absent	absent	absent	no	no	>3 days
97	11/25/2019	registred	985723	19	primigravida	1st	pre- obesity		200					no	No	No	72	100	70	78	110	80	2	6.5	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
98	12/1/2019	registred	986915	22	multigravida	2nd	normal		150					no	No	No	82	110	88	90	120	80	0	0.9	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
99	12/2/2019	registred	986955	22	multigravida	2nd	pre- obesity	100						no	No	No	80	108	78	94	120	80	1	6.4	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
100	12/6/2019	registred	984425	21	multigravida	2nd	normal			350			80	no	No	No	118	78	88	120	80	0.1	3.2	0	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
101	12/6/2019	registred	988082	26	primigravida	1st	pre- obesity	100						no	No	No	76	112	78	82	110	70	1	1.6	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
102	12/3/2019	registred	987292	18	primigravida	1st	pre- obesity		300				76	no	No	No	138	86	84	100	70	0.3	8	0	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
103	12/6/2019	registred	988093	25	multigravida	2nd	normal			250				no	No	No	82	110	74	80	110	70	2	7	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
104	12/7/2019	unregistered	988189	31	multigravida	2nd	pre- obesity						550	no	yes	No	88	116	78	86	118	80	4	16	absent	absent	absent	absent	absent	absent	no	no	</= 3 days
105	12/12/2019	unregistered	989301	22	multigravida	2nd	pre- obesity		200					no	no	No	86	110	80	90	120	80	2	4	absent	absent	present	absent	absent	absent	yes	no	>/=3 days

PLACEBO GROUP

																	pre delivery			post delivery			Laboratory parameters		Adverse effects								
sl no	date of admission	registered/ unregistered	IP no.	age	Gravida	Gravidity	BMI (kg/m2)	mean blood loss (ml)						Type of PPH			pulse	SBP	DBP	pulse	SBP	DBP	mean change in Hb	Mean change PCV	nausea	vomiting	dizziness	Nausea + vomiting	Nausea +dizziness	Vomiting +dizziness	Blood transfusion	additonal uterotonics - yes or no	Hospital stay- </= 3 days or > 3 days
								<100	100-150	151-200	201-300	300-500	>500	atonic	Truamtic	atonic + truamatic	beats/minute	mmHg	mmHg	beats/minute	mmHg	mmHg											
1	1/24/2019	registered	924436	21	primigravida	1st	normal				230			No	No	No	86	118	70	74	120	70	3.2	8.8	Absent	Absent	Absent	Absent	Absent	Absent	NO	no	</= 3 days
2	1/30/2019	registered	925534	20	primigravida	1st	normal				280			No	No	No	78	120	76	70	100	60	2.2	6.1	Absent	Absent	Absent	Absent	Absent	Absent	NO	no	</= 3 days
3	1/30/2019	registered	925637	24	multigravida	2nd	normal			200				No	No	No	86	108	78	70	120	70	1.5	3.6	Absent	Absent	Absent	Absent	Absent	Absent	NO	no	</= 3 days
4	3/1/2019	registered	931366	22	multigravida	2nd	normal				220			No	No	No	74	100	78	84	110	70	-1	-0.2	Absent	Absent	Absent	Absent	Absent	Absent	NO	no	</= 3 days
5	3/2/2019	unregistered	931591	22	multigravida	2nd	normal						650	yes	No	No	72	108	70	90	110	70	3.5	10.8	Absent	Absent	Absent	Absent	Absent	Absent	yes	yes	>3 days
6	3/6/2019	registered	932040	23	primigravidagravida	1st	normal			200				no	No	No	90	110	78	88	118	76	0	3.2	Absent	Absent	Absent	Absent	Absent	Absent	NO	no	</= 3 days
7	3/6/2019	registered	932212	25	multigravidagravida	3rd	normal				280			no	No	No	88	106	80	88	90	60	1.1	1	Absent	Absent	Absent	Absent	Absent	Absent	NO	no	</= 3 days
8	3/8/2019	registered	932757	24	multigravida	3rd	normal						550	no	yes	no	80	116	72	90	120	70	2.2	4.2	Absent	Absent	Absent	Absent	Absent	Absent	yes	no	>3 days
9	3/10/2019	registered	932947	22	multigravida	2nd	normal		150					no	no	no	78	100	70	70	110	90	0.3	1	Absent	present	Absent	Absent	Absent	Absent	no	yes	</= 3 days
10	3/13/2019	unregistered	933755	29	multigravida	4th	normal				250			no	no	no	68	108	78	90	110	60	1.9	1	Absent	Absent	Absent	Absent	Absent	Absent	no	no	</= 3 days
11	3/15/2019	registered	934116	21	primigravida	1st	<18.5					300		no	no	no	88	108	68	90	130	80	2.8	6.1	Absent	Absent	Absent	Absent	Absent	Absent	no	no	</= 3 days
12	3/19/2019	unregistered	934935	24	primigravida	1st	pre obesity				250			no	no	no	76	100	80	96	134	84	2.9	7.1	Absent	Absent	present	Absent	Absent	Absent	no	no	</= 3 days
13	4/1/2019	registered	937290	26	multigravida	2nd	normal			200				no	no	no	86	112	86	86	114	70	2.9	7	Absent	Absent	Absent	Absent	Absent	Absent	no	no	</= 3 days
14	4/7/2019	registered	938402	26	multigravida	2nd	normal					300		no	no	no	84	100	68	90	120	70	1.6	1.1	Absent	Absent	Absent	Absent	Absent	Absent	no	no	>3 days
15	**4/30/2019**	**unregistered**	**942995**	**20**	**primigravida**	**1st**	**normal**					**400**		**no**	**no**	**no**	**82**	**116**	**82**	**80**	**100**	**70**	**1.5**	**5.9**	**Absent**	**Absent**	**Absent**	**Absent**	**Absent**	**Absent**	**no**	**no**	**</= 3 days**
16	5/1/2019	unregistered	943159	22	multigravida	2nd	Class 1	100						no	no	no	76	116	78	80	112	78	0.9	0.5	Absent	Absent	Absent	Absent	Absent	Absent	no	no	</= 3 days
17	5/4/2019	registered	943965	28	multigravida	2nd	normal					350		no	no	no	66	100	78	82	110	70	1.3	1	Absent	Absent	Absent	Absent	Absent	Absent	no	no	</= 3 days
18	5/5/2019	unregistered	944019	22	multigravida	2nd	Class 1						650	no	yes	no	68	116	74	110	100	60	0.9	4.5	Absent	Absent	Absent	Absent	Absent	Absent	yes	no	>3 days
19	5/2/2019	unregistered	943517	25	primigravida	1st	normal					450		no	no	no	78	100	78	112	100	60	1.4	4.9	Absent	Absent	Absent	Absent	Absent	Absent	no	no	</= 3 days
20	5/8/2019	unregistered	944689	23	multigravida	2nd	Class 1				250			no	no	no	88	116	78	78	116	78	2.4	7.4	Absent	Absent	Absent	Absent	Absent	Absent	no	no	</= 3 days
21	5/13/2019	registered	945632	24	primigravida	1st	normal					350		no	no	no	90	108	80	80	120	70	2.4	0	Absent	Absent	Absent	Absent	Absent	Absent	no	no	</= 3 days
22	5/15/2019	unregistered	946010	24	multigravida	2nd	normal					350		no	no	no	78	100	88	80	110	70	1.2	0.4	Absent	Absent	Absent	Absent	Absent	Absent	no	no	</= 3 days
23	5/17/2019	registered	946613	22	multigravida	2nd	pre obesity					400		no	no	no	78	116	76	100	120	70	0.3	3	Absent	Absent	Absent	Absent	Absent	Absent	no	no	</= 3 days
24	5/18/2019	registered	946852	26	multigravida	3rd	normal					400		no	no	no	76	116	78	80	110	70	1.6	6	Absent	Absent	Absent	present	Absent	Absent	no	no	</= 3 days
25	5/21/2019	registered	947250	28	primigravida	1st	pre obesity					400		no	no	no	84	100	82	80	100	60	4	10.6	Absent	Absent	Absent	Absent	Absent	Absent	no	no	</= 3 days
26	5/22/2019	registered	947476	26	multigravida	2nd	pre obesity		200					no	no	no	88	100	78	92	110	70	2	6	Absent	Absent	Absent	Absent	Absent	Absent	no	no	</= 3 days
27	5/22/2019	unregistered	947659	24	multigravida	3rd	normal					350		no	no	no	78	110	78	86	116	78	1.4	2.5	Absent	Absent	Absent	Absent	Absent	Absent	no	no	</= 3 days
28	5/23/2019	unregistered	947851	21	multigravida	3rd	normal					400		no	no	no	74	116	74	92	118	78	2.2	3.8	Absent	Absent	Absent	Absent	Absent	Absent	no	no	</= 3 days
29	5/27/2019	unregistered	948492	19	multigravida	2nd	normal				380			no	no	no	76	128	80	56	120	70	1.9	3.2	Absent	Absent	Absent	Absent	Absent	Absent	no	no	</= 3 days
30	5/28/2019	unregistered	948816	25	multigravida	2nd	pre obesity					450		no	no	no	74	118	70	80	110	70	2.4	4	Absent	Absent	present	Absent	Absent	Absent	no	no	</= 3 days
31	**6/1/2019**	**registered**	**949461**	**25**	**multigravida**	**3rd**	**pre obesity**			**200**				**no**	**no**	**no**	**76**	**118**	**70**	**74**	**120**	**70**	**0.9**	**1.4**	**Absent**	**Absent**	**Absent**	**Absent**	**Absent**	**Absent**	**no**	**no**	**>3 days**
32	6/7/2019	unregistered	950645	22	primigravida	1st	normal				250			no	no	no	88	100	70	84	120	88	3.4	12	Absent	Absent	Absent	Absent	Absent	Absent	no	yes	</= 3 days
33	6/10/2019	unregistered	951248	22	primigravida	1st	pre obesity			200				no	no	no	86	110	78	82	122	86	1.8	7.3	present	Absent	Absent	Absent	Absent	Absent	no	yes	</= 3 days
34	6/17/2019	unregistered	952637	22	primigravida	1st	normal						550	no	yes	no	88	108	70	76	116	78	3.1	10.6	Absent	Absent	present	Absent	Absent	Absent	no	no	</= 3 days
35	7/1/2019	registered	955292	24	primigravida	1st	normal				350			no	no	no	70	108	78	80	116	74	4.5	14.2	Absent	Absent	Absent	Absent	Absent	Absent	yes	yes	>3 days
36	7/8/2019	unregistered	956590	26	multigravida	3rd	normal		150					no	no	no	78	130	70	88	120	70	0.5	9.4	Absent	Absent	Absent	Absent	Absent	Absent	no	no	</= 3 days
37	7/9/2019	registered	956887	25	multigravida	2nd	normal				300			no	no	no	84	108	70	86	116	78	2.3	4.9	Absent	Absent	Absent	Absent	Absent	Absent	no	no	</= 3 days
38	7/15/2019	registered	957942	22	primigravida	1st	normal				350			no	no	no	88	118	76	78	100	76	3.3	0.5	Absent	Absent	Absent	Absent	Absent	Absent	no	no	</= 3 days
39	7/13/2019	registered	957822	21	primigravida	1st	normal				350			no	no	no	78	126	78	76	108	74	3.2	13.3	present	Absent	Absent	Absent	Absent	Absent	no	yes	</= 3 days
40	7/15/2019	registered	958205	20	multigravida	2nd	pre obesity	100						no	no	no	80	116	78	88	116	72	0.5	0	Absent	Absent	Absent	Absent	Absent	Absent	no	no	</= 3 days
41	7/17/2019	registered	958574	20	multigravida	2nd	<18.5					450		no	no	no	78	116	78	70	116	74	3.8	13	Absent	Absent	Absent	Absent	Absent	Absent	no	no	</= 3 days
42	7/17/2019	unregistered	958669	24	multigravida	2nd	pre obesity					400		no	no	no	84	110	78	84	120	70	1.6	3.8	Absent	Absent	Absent	Absent	Absent	Absent	no	no	</= 3 days
43	7/19/2019	unregistered	959125	24	primigravida	1st	pre obesity				300			no	no	no	88	108	76	90	116	74	2.3	6.8	Absent	Absent	Absent	Absent	Absent	Absent	no	no	</= 3 days
44	7/22/2019	unregistered	959760	22	primigravida	1st	normal				300			no	no	no	86	126	70	80	100	70	1.9	4.7	Absent	present	Absent	Absent	Absent	Absent	no	no	>3 days
45	7/23/2019	unregistered	960165	23	multigravida	3rd	pre obesity			250				no	no	no	90	100	68	70	120	76	1.1	2.5	Absent	Absent	Absent	Absent	Absent	Absent	no	no	</= 3 days
46	8/5/2019	unregistered	962248	26	primigravida	1st	Class 1						600	no	no	yes	84	104	80	76	110	70	2.2	6.1	Absent	Absent	Absent	Absent	Absent	Absent	no	no	>3 days
47	8/7/2019	registered	962694	22	multigravida	2nd	normal						650	yes	no	no	88	100	70	78	116	74	4	12	present	Absent	Absent	Absent	Absent	Absent	yes	no	</= 3 days

48	8/18/2019	unregistered	963781	23	primigravida	1st	pre obesity					400		no	no	no	86	108	78	78	100	66	3.5	8.4	Absent	Absent	Absent	Absent	Absent	Absent	no	no	</= 3 days
49	8/16/2019	unregistered	964328	25	primigravida	1st	pre obesity					450		no	no	no	78	120	78	88	110	70	3.6	11.3	Absent	Absent	Absent	Absent	Absent	Absent	no	yes	</= 3 days
50	8/18/2019	registered	964581	20	primigravida	1st	normal				300			no	no	no	76	108	74	88	110	74	0.3	0	Absent	Absent	Absent	Absent	Absent	Absent	no	no	</= 3 days
51	8/17/2019	registered	964583	22	multigravida	2nd	normal						600	yes	no	no	78	110	70	86	100	70	2.2	4	Absent	Absent	Absent	Absent	Absent	Absent	no	yes	</= 3 days
52	8/19/2019	registered	965011	21	primigravida	1st	normal					400		no	no	no	76	102	70	80	116	78	5.1	12.2	Absent	Absent	Absent	Absent	Absent	Absent	no	yes	</= 3 days
53	8/27/2019	registered	966880	28	multigravida	5th	normal					400		no	no	no	88	108	70	88	126	82	2.6	2.2	Absent	Absent	Absent	Absent	Absent	Absent	no	no	</= 3 days
54	8/29/2019	registered	967252	22	primigravida	1st	Class 1				300			no	no	no	84	106	72	68	118	80	0.9	0	Absent	Absent	Absent	Absent	Absent	Absent	no	no	</= 3 days
55	9/8/2019	registered	969381	25	multigravida	3rd	normal					400		no	no	no	86	106	74	86	120	70	0.9	3.7	Absent	Absent	Absent	Absent	Absent	Absent	no	no	</= 3 days
56	9/8/2019	registered	969309	21	primigravida	1st	normal						600	yes	no	no	88	110	70	66	110	70	3.4	15.5	Absent	Absent	Absent	Absent	Absent	Absent	yes	no	>3 days
57	9/9/2019	unregistered	969405	26	primigravida	1st	normal					450		no	no	no	78	100	70	90	110	70	3.6	24.1	Absent	Absent	Absent	Absent	Absent	Absent	no	yes	</= 3 days
58	9/12/2019	registered	970297	22	multigravida	3rd	pre obesity			200				no	no	no	76	100	78	78	110	80	1.8	5	Absent	Absent	Absent	Absent	Absent	Absent	no	no	</= 3 days
59	9/16/2019	registered	970997	35	primigravida	1st	Class 1				350			no	no	no	86	100	84	88	112	80	1.6	2	Absent	Absent	Absent	Absent	Absent	Absent	no	no	</= 3 days
60	9/17/2019	registered	971579	21	primigravida	1st	normal					400		no	no	no	82	116	82	90	110	84	3.7	8.2	Absent	Absent	Absent	Absent	Absent	Absent	no	no	>3 days
61	9/20/2019	unregistered	972159	21	multigravida	2nd	pre obesity				300			no	no	no	86	104	70	82	110	70	0.9	4,9	Absent	Absent	Absent	Absent	Absent	Absent	no	no	</= 3 days
62	9/21/2019	registered	971289	20	primigravida	1st	normal						650	yes	no	no	78	108	80	90	110	66	0.6	1	Absent	Absent	Absent	Absent	Absent	Absent	no	no	</= 3 days
63	9/30/2019	unregistered	974217	25	multigravida	2nd	normal	100						no	no	no	78	110	78	78	120	76	0.4	0	Absent	Absent	Absent	Absent	Absent	Absent	no	no	</= 3 days
64	9/30/2019	registered	973575	25	multigravida	4th	normal		200					no	no	no	68	100	78	80	110	70	0.2	6.4	Absent	Absent	Absent	Absent	Absent	Absent	no	no	</= 3 days
65	10/3/2019	unregistered	975021	19	primigravida	1st	<18.5			200				No	no	no	70	100	78	74	110	76	0.1	0.7	Absent	Absent	Absent	Absent	Absent	Absent	no	no	</= 3 days
66	10/4/2019	registered	975222	20	primigravida	1st	Class 1			300				No	no	no	66	118	76	80	100	70	1.3	3.3	Absent	present	Absent	Absent	Absent	Absent	no	no	</= 3 days
67	10/4/2019	unregistered	975021	19	primigravida	1st	normal						550	yes	no	no	72	108	70	86	110	70	0.6	3	Absent	Absent	Absent	Absent	Absent	Absent	yes	no	>3 days
68	10/4/2019	registered	975203	27	multigravida	2nd	normal				350			No	no	no	70	100	78	84	110	74	0	0	Absent	Absent	Absent	Absent	Absent	Absent	no	yes	</= 3 days
69	10/5/2019	unregistered	975343	30	multigravida	3rd	normal						550	yes	no	no	78	108	78	88	120	70	0.6	3.4	Absent	Absent	Absent	Absent	Absent	Absent	yes	no	>3 days
70	10/6/2019	unregistered	975479	28	multigravida	2nd	normal				300			no	no	no	78	110	76	88	100	70	0.4	0.3	Absent	Absent	Absent	Absent	Absent	Absent	no	no	</= 3 days
71	10/10/2019	registered	976109	21	multigravida	2nd	pre obesity		200					no	no	no	86	120	80	72	120	70	0.8	3.5	Absent	Absent	Absent	Absent	Absent	Absent	no	no	</= 3 days
72	10/11/2019	unregistered	976555	23	multigravida	2nd	pre obesity			250				no	no	no	84	136	78	76	120	70	0.4	4.1	Absent	Absent	Absent	Absent	Absent	Absent	no	no	</= 3 days
73	10/13/2019	registered	977399	24	multigravida	2nd	normal			250				no	no	no	88	136	74	80	110	70	2.6	2.6	Absent	Absent	Absent	Absent	Absent	Absent	no	no	</= 3 days
74	10/17/2019	registered	977899	26	multigravida	3rd	pre obesity			250				no	no	no	84	108	78	88	120	70	1.6	3.2	Absent	Absent	Absent	Absent	Absent	Absent	no	no	</= 3 days
75	10/18/2019	registered	978175	21	primigravida	1st	normal			250				no	no	no	82	110	78	82	100	76	3.3	9.2	Absent	Absent	Absent	Absent	Absent	Absent	yes	yes	>3 days
76	10/19/2019	registered	978232	21	primigravida	1st	normal					450		no	no	no	80	118	78	86	110	70	2.2	4.4	Absent	Absent	Absent	Absent	Absent	Absent	no	no	</= 3 days
77	10/21/2019	unregistered	978470	26	multigravida	2nd	normal			250				no	no	no	82	110	78	80	120	70	3	10.1	Absent	Absent	Absent	Absent	Absent	Absent	no	no	</= 3 days
78	10/25/2019	registered	979362	27	primigravida	1st	normal				350			no	no	no	76	100	70	74	120	70	4.6	8.1	Absent	Absent	Absent	Absent	Absent	Absent	yes	yes	>3 days
79	10/25/2019	unregistered	979452	24	multigravida	2nd	normal			250				no	no	no	68	118	68	76	100	70	0.7	3.4	Absent	Absent	Absent	Absent	Absent	Absent	no	no	>3 days
80	10/31/2019	registered	979754	26	multigravida	2nd	normal			250				no	no	no	82	108	76	68	116	74	0.4	2.1	Absent	Absent	Absent	Absent	Absent	Absent	no	no	</= 3 days
81	10/31/2019	registered	980527	28	primigravida	1st	normal				300			no	no	no	88	120	70	82	110	70	2.6	11	Absent	Absent	Absent	Absent	Absent	Absent	no	no	</= 3 days
82	10/31/2019	unregistered	980525	21	multigravida	3rd	normal	150						no	no	no	76	108	76	74	110	70	0	0	Absent	Absent	Absent	Absent	Absent	Absent	no	no	</= 3 days
83	11/2/2019	registered	980816	21	multigravida	2nd	pre obesity				400			no	no	no	68	120	78	86	120	70	2.4	#REF!	Absent	Absent	Absent	Absent	Absent	Absent	no	no	</= 3 days
84	11/2/2019	unregistered	980921	21	multigravida	2nd	pre obesity			300				no	no	no	82	110	76	86	110	78	2.1	3	Absent	Absent	Absent	Absent	Absent	Absent	no	no	</= 3 days
85	11/2/2019	unregistered	981298	22	primigravida	1st	normal			200				no	no	no	80	116	78	80	110	89	0.9	5	Absent	Absent	Absent	Absent	Absent	Absent	no	no	>3 days
86	11/5/2019	unregistered	981368	20	primigravida	1st	pre obesity					350		no	no	no	78	100	64	84	110	70	3.5	9.4	Absent	Absent	Absent	Absent	Absent	Absent	no	no	</= 3 days
87	11/6/2019	unregistered	981777	23	multigravida	2nd	normal					300		no	no	no	82	108	76	86	100	60	1.5	6.2	Absent	Absent	Absent	Absent	Absent	Absent	no	no	</= 3 days
88	11/9/2019	registered	982429	25	primigravida	1st	Class 1					400		no	no	no	70	108	78	78	100	76	1	2	Absent	present	Absent	Absent	Absent	Absent	no	no	</= 3 days
89	11/9/2019	unregistered	982513	24	multigravida	2nd	Class 1				250			no	no	no	68	120	78	80	100	70	0.6	0.2	Absent	Absent	Absent	Absent	Absent	Absent	no	no	</= 3 days
90	11/10/2019	registered	982514	20	primigravida	1st	normal			200				no	no	no	74	120	78	86	116	80	1.2	4	Absent	Absent	Absent	Absent	Absent	Absent	no	no	>3 days
91	11/11/2019	registered	983175	21	primigravida	1st	normal		150					no	no	no	80	138	86	90	110	70	1.3	1.2	Absent	Absent	Absent	Absent	Absent	Absent	no	no	</= 3 days
92	11/11/2019	unregistered	983571	26	multigravida	2nd	normal		150					no	no	no	80	116	74	86	112	70	1.4	4	Absent	Absent	Absent	Absent	Absent	Absent	no	no	</= 3 days
93	11/15/2019	unregistered	983740	30	multigravida	3rd	normal			200				no	no	no	78	100	70	86	130	70	2.8	5	Absent	Absent	Absent	Absent	Absent	Absent	no	no	</= 3 days
94	11/16/2019	registered	984061	21	primigravida	1st	normal			200				no	no	no	72	116	74	94	118	80	1.1	3.7	Absent	Present	Absent	Absent	Absent	Absent	no	no	</= 3 days
95	11/16/2019	registered	984110	32	multigravida	2nd	pre obesity				400			no	no	no	76	128	80	76	118	80	0.9	0.1	Absent	Absent	Absent	Absent	Absent	Absent	no	no	</= 3 days
96	11/16/2019	registered	985406	28	multigravida	2nd	normal	100						no	no	no	78	110	70	80	116	70	0.3	2.2	Absent	Absent	Absent	Absent	Absent	Absent	no	no	</= 3 days
97	11/20/2019	registered	985583	26	multigravida	4th	pre obesity				400			no	no	no	76	100	68	84	110	70	1.4	4.2	Absent	Absent	Absent	Absent	Absent	Absent	no	no	</= 3 days
98	11/25/2019	unregistered	986476	25	multigravida	4th	normal			350				no	no	no	70	112	76	76	110	70	1.6	7.1	Absent	Absent	Absent	Absent	Absent	Absent	no	no	>3 days
99	11/27/2019	unregistered	986695	23	multigravida	3rd	normal				400			no	no	no	72	108	68	92	120	80	2.7	10.1	present	Absent	Absent	Absent	Absent	Absent	no	yes	>3 days
100	11/28/2019	registered	959833	19	primigravida	1st	pre obesity		200					no	no	no	68	100	68	70	100	68	1.7	3.2	Absent	Absent	Absent	Absent	Absent	Absent	no	no	</= 3 days
101	11/30/2019	unregistered	987202	20	primigravida	1st	pre obesity				400			no	no	no	78	120	66	86	112	76	2	5.1	Absent	Absent	Absent	Absent	Absent	Absent	no	no	</= 3 days
102	11/30/2019	registered	987245	30	multigravida	2nd	normal					450		no	no	no	76	128	88	86	120	80	2.2	4.2	Absent	Absent	Absent	Absent	Absent	Absent	no	no	</= 3 days
103	12/6/2019	unregistered	988115	21	primigravida	1st	pre obesity				400			no	no	no	80	120	76	82	120	70	1.1	7.6	Absent	Absent	Absent	Absent	Absent	Absent	no	no	</= 3 days
104	12/8/2019	unregistered	988370	19	primigravida	1st	pre obesity			350				no	no	no	90	120	76	94	100	60	0.9	10.1	Absent	Absent	Absent	Absent	Absent	Absent	no	no	</= 3 days
105	12/9/2019	registered	988521	21	primigravida	1st	pre obesity						900	yes	no	no	90	116	74	106	100	76	2.6	9.4	Absent	Absent	Absent	Absent	Absent	Absent	no	no	</= 3 days