“COMPARISON OF EFFICACY AND SAFETY OF INTRAVENOUS FERRIC CARBOXYMALTOSE VS IRON SUCROSE IN THE TREATMENT OF ANTEPARTUM IRON DEFICIENCY ANAEMIA – A RANDOMIZED CONTROLLED TRIAL”

REG.NO. BJ0112003

Dissertation

Submitted to the
KLE University, Belgaum, Karnataka

In Partial Fulfillment
of the requirements for the degree of

MASTER OF SURGERY
in
OBSTETRICS AND GYNAECOLOGY

**DEPARTMENT OF OBSTETRICS AND GYNAECOLOGY,
JAWAHARLAL NEHRU MEDICAL COLLEGE,
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ENDORSEMENT

This is to certify that the dissertation entitled **"COMPARISON OF EFFICACY AND SAFETY OF INTRAVENOUS FERRIC CARBOXYMALTOSE VS IRON SUCROSE IN THE TREATMENT OF ANTEPARTUM IRON DEFICIENCY ANAEMIA – A RANDOMIZED CONTROLLED TRIAL"** is a bonafide research work done by **CANDIDATE REG NO. BJ0112003**.

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LIST OF ABBREVIATIONS USED

APH	-	Antepartum haemorrhage
B.C	-	Before Christ
BMI	-	Body mass index
cms	-	Centimeters
DBP	-	Diastolic blood pressure
DLHS	-	District Level Household Survey
EDD	-	Estimated date of delivery
FCM	-	Ferric carboxymaltose
g/dL	-	Gram per deciliter
gms	-	Grams
Hb	-	Haemoglobin
i.v.	-	Intravenous
ICMR	-	Indian Council of Medical Research
IDA	-	Iron deficiency anaemia
IPC	-	Iron III Polymaltose complex
IPD	-	In patient department
IS	-	Iron sucrose
Kg	-	Kilograms
kg/ m^2	-	Kilograms per square meter
LMP	-	Last menopausal date
MCV	-	Mean corpuscular volume
mg	-	Milligram
min	-	Minutes
ml	-	Milliliter

NS	-	Normal saline
n	-	Total number
NFHS	-	National Family Health Survey
NNMB	-	National Nutrition Monitoring Bureau
NO	-	Nitric oxide
NOAELs	-	No-Observed-Adverse-Effect-Levels
OPD	-	Out patient department
p	-	Probability
PCV	-	Packed cell volume
PIH	-	Pregnancy induced hypertension
PPH	-	Postpartum hemorrhages
RBC	-	Red blood cell
RBC	-	Red blood count
RES	-	Reticulo-endothelial system
SBP	-	Systolic blood pressure
SD	-	Standard deviation
US	-	United States
USA	-	United States of America
vs	-	Versus
WHO	-	World Health Organization
wk	-	Week
µg/L	-	Microgram per deciliter

ABSTRACT

Background and objectives

Ferric carboxymaltose has been recently introduced for the treatment of anaemia. The present study was planned to compare the efficacy, tolerability and safety of intravenous ferric carboxymaltose with intravenous iron sucrose in the treatment of iron deficiency anaemia among pregnant women.

Methodology

The present one year randomized control trial was done from January 2013 to July 2014 in the department of Obstetrics and Gynaecology, KLES Dr Prabhakar Kore Hospital and Medical Research Centre, Belgaum. A total of 305 pregnant women were randomized into two groups comprising of 158 in group C (Received iron carboxymaltose transfusion) and 147 in Group S (Received iron sucrose transfusion). The outcome data was available among 153 in group C and 139 in group S.

Results

In the present study the commonest age group was 26 to 30 years in group C comprised of 40.52% compared to 21 to 25 years in group S with 38.85% of the women (p=0.312) and mean age of the study population in group C and S was comparable (25.33±3.53 vs 24.85±4.18 years; p=0.082) The socio demographic characteristics, obstetric history, vitals and pretreatment heamoglobin were comparable in both the groups (p>0.050). The post treatment haemoglobin levels in 54.9% of the women were found to be 11 or more in group C compared to 56.12% in group S (p=0.614) and mean post treatment haemoglobin levels were

comparable in group C and group S (11.59±7.72 vs 11.02±0.75 gm%; p=0.358). Significantly higher number of women in group C had increase in haemoglobin levels between 2.0 to 2.5 gm% (56.86%) and the mean increase in haemoglobin levels post treatment was significantly high in group C (2.27 ± 0.39 gm%) (p<0.050). Also the mean percentage change in haemoglobin levels post treatment was significantly high in group C (26.54 ± 5.98 percent) (p=0.029). The side effects were comparable in group C and S (p=0.536) but significantly higher number of women had pyrexia in group C (8.5%) (p=0.041).

Conclusion and interpretation

Intravenous iron carboxymaltose is more effective in the treatment of iron deficiency anaemia among pregnant women compared to intravenous iron sucrose. Further it is well tolerated in pregnant women as side effects are comparable to that of iron sucrose except pyrexia.

Keywords:

Intravenous iron sucrose; Iron carboxymaltose; Iron deficiency anaemia;

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INTRODUCTION

Iron is an essential element for the functioning of all types of cells in the body. It plays a vital role in cell cycle regulation, electron transport in the respiratory chain, DNA synthesis and other metabolic reaction. The functioning of the oxygen binding molecules such as haemoglobin largely depends on the availability of iron. Anaemia is a condition in which the number of red blood cells or their oxygen-carrying capacity is insufficient to meet physiologic needs.[1-3] It is one of the commonest medical disorder among pregnant women in India. Iron deficiency anaemia is accompanied by depleted iron stores and signs of a compromised supply of iron to the tissues.[1] There is physiological variation in haemoglobin levels during pregnancy; at the beginning of a pregnancy, there is a normal reduction in haemoglobin level followed by a slight rise towards the end of pregnancy due to increased haemoconcentration.[2] The initial reduction has been explained to result from increased red cell mass and demands of the fetus which exceeds iron intake with consequent reduction in iron stores of the woman's body.[2]

Anaemia is the most common nutritional deficiency disorder in the world. World Health Organization (WHO) has estimated that prevalence of anaemia in developed and developing countries in pregnant women is 14% and 51%. Its alarming to know that the prevalence in India is as high as 65 to 75% .[4]

Prevalence of anaemia in South Asian countries is highest compared to the countries. WHO estimates that even among the South Asian countries, India has the highest prevalence of anaemia. What is even more important is the fact that almost 50 % of the global maternal deaths due to anaemia occur in South Asian countries.[5]

It is apparent that India's contribution to the prevalence of anaemia in pregnancy and maternal deaths due to anaemia is higher than warranted by the size of its population.[3] On hand estimates also suggest that the magnitude of reduction in the prevalence of anaemia during nineties in India is lower than that in neighboring South East Asian countries. In view of the high prevalence of anaemia in the country, five major surveys National Family Health Survey (NFHS) 2 and 3,[6,7] District Level Household Survey 2 (DLHS),[8] Indian Council of Medical Research (ICMR) Micronutrient Survey[9] and Micronutrient Survey conducted by National Nutrition Monitoring Bureau (NNMB)[10] were undertaken to find the prevalence of anaemia in the country. The results of these surveys showed that over 70% of pregnant women and adolescent girls in the country were anaemic.

Anaemia gets aggravated by increased requirements during adolescence and during pregnancy.[8] Assuming that the absorption of iron is 8% in pregnant women, their normal dietary intake will meet only 30-45% of the requirement.[4]

There are two known factors which play a role in the development of iron deficiency anaemia (IDA) in pregnancy; the first is the woman's iron stores at the beginning of conception and the second is the amount of iron absorbed during gestation. Women in developing countries are not commonly affected by anaemia in pregnancy is an indication that preexisting iron stores are often insufficient and physiological adaptations to pregnancy is lacking to meet the increased requirements.[11]

Anaemia in pregnancy is associated with unfavorable consequences both for the mother and the foetus. Studies have shown that the adverse consequences of

maternal anaemia may affect not only the neonate and infant but also increase the risk of non communicable diseases when the child grows into an adult and the risk of low birth weight in the next generation. The detection of anaemia and its effective management is available, affordable and it is possible to effectively implement these even in the rural setting. Not to mention the fact that these are very cost effective interventions.[4]

There are various promising forms of treatment for iron deficiency anaemia. Oral iron is the most preferred route of administration for mild anaemia. Treatment with iron preparations is used routinely in pregnancy. However, oral iron supplementation often leads to adverse side effects, such as constipation, abdominal pain and other gastrointestinal symptoms. Because of these unwarranted gastrointestinal effects the compliance to iron treatment is highly variable.

Intravenous iron preparations show good potential, especially in cases of severe anaemia. They provide a greater and more rapid iron supply than oral iron therapy without the gastrointestinal side effects of oral preparations and make it possible to avoid blood transfusion which is associated with risks.[12] To date, many studies have focused on the use of i.v, iron and its side effects and safety in pregnant women. Iron sucrose has been used for years for i.v. treatment of iron deficiency in pregnant women after the first trimester. However, its use is limited by the low maximum dosage due to local and systemic side effects in higher doses. In order to avoid these adverse effects the drug has to be administered in multiple infusions of lower doses less than 200 mg per day. Hence it increases the number of days of admission in the hospital and it becomes an extra burden on the hospital resources.

The search for an ideal parentral iron preparation has led to the introduction of ferric carboxymaltose. It comprises a macromolecular iron-hydoxide complex of polynuclear iron hydroxide tightly bound in a carbohydrate shell. This new complex has a molecular weight of 150,000 Daltons. This design allows for a controlled delivery of iron within the cells of reticulo-endothelial system and hence subsequent delivery to the iron binding proteins, with a minimal risk of release of large amounts of ionic iron in the serum. This iron preparation can be used intravenously in high doses with up to 1000 mg infused in l-5 min with low risk of side effects. Its use is approved in the second and third trimesters of pregnancy.[13] However, there is limited evidence of randomised trials concerning the clinical use of ferric carboxymaltose in pregnant women. The aim of our study is, therefore, to compare i.v. ferric carboxymaltose with i.v. iron sucrose during pregnancy regarding the efficacy, tolerability and safety profile.

OBJECTIVES

The objectives of the present study were;

Primary

To evaluate the efficacy of intravenous iron carboxymaltose compared with intravenous ferric sucrose in treating iron deficiency anaemia in pregnant women. The mean rise in haemoglobin at the end of four weeks is an important parameter to evaluate the efficacy of the therapy.

Secondary

To investigate the safety in terms of local and systemic reactions and tolerability of iron carboxymaltose compared with ferric sucrose.

REVIEW OF LITERATURE

Maternal mortality is defined as "The death of a woman while pregnant or within 42 days of termination of pregnancy, irrespective of the duration and the site of the pregnancy, from any cause related to or aggravated by the pregnancy or its management, but not from accidental or incidental causes." It continues to be a major health problem in the developing world. Nearly 600,000 women die each year as a result of complications of pregnancy and childbirth; most of these deaths could be prevented with adequate resources and skills. The worldwide maternal mortality ratio (annual number of deaths of women from pregnancy-related causes per 100,000 live births) is estimated to be 390 per 100,000 live births.[14]

Most of these maternal deaths occur in developing countries, where the risk of dying for a woman in pregnancy and childbirth is 50–100 times greater than that of women in the developed world. In the developing world, rates as high as 700 per 100,000 live births in many parts of Africa and in some countries in south Asian continent have been reported. These large differences found are related primarily to differences in available obstetric care for women living in areas with inadequate antenatal and delivery care services.[14]

In 1987, international agencies and leaders from 45 countries established the Safe Motherhood initiative with the goal of reducing half of maternal deaths by the year 2000.[15] A key element of Safe Motherhood is the eradication of anaemia during pregnancy. The WHO has produced estimates of the global burden of deaths attributable to anaemia (all forms) in women of reproductive age. The total estimate

is a minimum of 16,800 and maximum of 28,000 annually with a greater risk of anaemia-related death in younger women.[14]

Anaemia is defined by WHO as haemoglobin of less than 11 gm%, which vary by age, sex, altitude, smoking, and pregnancy status. Iron deficiency is thought to be the most common cause of anaemia globally, although other conditions, such as folate, vitamin B12 and vitamin A deficiencies, chronic inflammation, parasitic infections, and inherited disorders can all cause anaemia. In its severe form, it is associated with fatigue, weakness, dizziness and drowsiness. Pregnant women and children are particularly vulnerable.[16]

Anaemia is a global public health problem affecting both developing and developed countries with major consequences for human health as well as social and economic development. It occurs at all stages of the life cycle, but is more prevalent in pregnant women and young children.[17]

Historical perspectives[18]

Anaemia is as ancient as the human species is. Ancient people recognized blood as life and the thing containing soul. In Before Christ (B.C) era people had less knowledge about blood and its blood components. Iron deficiency anaemia is believed to be described in 1500 B.C. It was termed as chlorosis or green sickness in European countries.

History also reveals evidences that iron salts were used in treatment of chlorosis. Thomas Sydenham recommended iron salts for treatment of anaemia but it was controversial treatment until 20th century, till mechanism of action of iron in treatment of anaemia was fully understood. In seventeenth century William

Harvey proved the circulation of blood in the human body.[7] After this important discovery, study of blood and blood related disorders caught momentum and many inventions came up.

Some of the important historical inventions and discoveries are as follows:

- 1637-1680: Jan Swammerdam discovered "Ruddy Globules" after looking at blood through microscope. (Today's red blood count [RBCs])
- 1667: Richard Lower reported first heterologous transfusion from lamb to an insane man.
- 1739-74: William Hewson published his opinion posthumously that red cells were present in large number and it is important for RBCs to be in that number.
- 1818: James Blundell was the first to give human to human transfusion of blood in a case of postpartum hemorrhages (PPH).
- In 19th century term "Anaemia" was coined to refer the clinical condition with pallor of mucous membranes, nails etc
- 1900: Karl Landsteiner defined the blood groups and donor and recipient blood could be properly matched.
- 1937: First blood bank established in USA.

Era of modern hematology is considered to be originated from Harvard Medical School. George Richards Minot and his assistant William Murphy has outstanding contribution in modern hematology. In 20th century hematologists were

able to diagnose anaemia with simple, easier and faster laboratory tests and techniques. They were able to treat it with diet modifications and drug therapy. With further advancements, we are currently able to treat anaemia with modern modalities like Blood transfusion, Bone marrow transplantation.[19] Further, stem cell therapy will give us better and totally different modalities of treatment in hematology.

Anaemia in pregnancy

There is a physiological variations in haemoglobin levels during pregnancy; at the beginning of a pregnancy, there is a normal reduction in haemoglobin level followed by a slight increase towards the end of pregnancy.[2] The initial reduction has been explained to result from increased demands of the fetus which exceeds iron intake with consequent reduction in iron stores of the woman's body.[2] Thus, the World Health Organization has defined anaemia in pregnancy as a haemoglobin value below 11 g/dL.[1,3]

In most published studies, the mean minimum haemoglobin in healthy pregnant women living at sea level is 11-12g/dL.[20] The mean minimum acceptable haemoglobin level during pregnancy by WHO criteria is taken to be 11g/dL in the first half of pregnancy and 10.5 g/dL in the second half of pregnancy.[21]

Classification

The WHO further divide anaemia in pregnancy into:[21]

- Mild anaemia (haemoglobin 10-10.9g/dL)
- Moderate anaemia (haemoglobin 7.0-9.9g/dL)

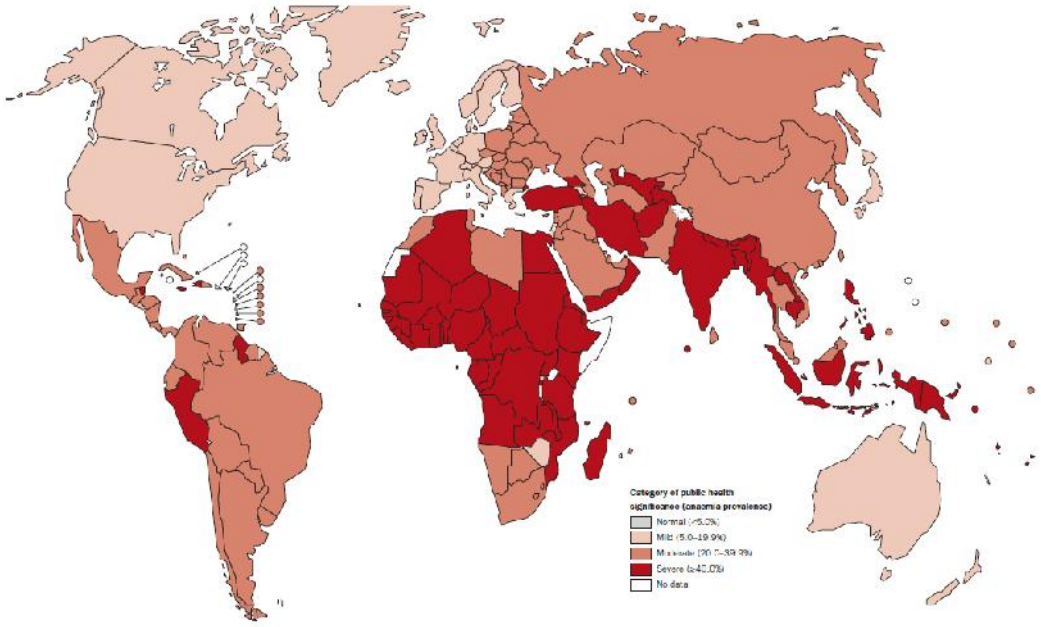
- Severe anaemia (haemoglobin < 7g/dL)

Epidemiology

Prevalence

Worldwide

World Health Organization in 2008 estimates showed that, *g*lobally, anaemia affects 1.62 billion people, which corresponds to 24.8% of the population. The highest prevalence is in preschool-age children (47.4%), and the lowest prevalence is in men (12.7%).[17]



Anaemia as a public health problem by country: Pregnant women[17]

Worldwide 41.8% of pregnant women are anaemic as compared with 30.2% non-pregnant women; the most severely affected areas are South-East Asia (48.2%) and Africa (57.1%). A large proportion of the 17.2 million anaemic pregnant women

in Africa live in the west African sub-region. The prevalence rate in some of the countries range from 50.2% in Togo, 66.7% in Nigeria, 68.3% in Burkina Faso, 72.7% in Benin and 75.1% in Gambia.[17]

South East Asia Region

Prevalence of anaemia in South Asian countries is among the highest in the world. WHO estimates that even among the South Asian countries, India has the highest prevalence of anaemia. What is even more important is the fact that about half of the global maternal deaths due to anaemia occur in South Asian countries; India contributes to about 80% of the maternal deaths due to anaemia in South Asia.[5]

Indian scenario

Prevalence of anaemia in all the groups is higher in India as compared to other developing countries.[22] It is obvious that India's contribution both to the prevalence of anaemia in pregnancy and maternal deaths due to anaemia is higher than warranted by the size of its population.[5] Available estimates also suggest that the magnitude of reduction in the prevalence of anaemia during nineties in India is lower than that in neighboring South East Asian countries.[4]

Worried about the estimated high prevalence of anaemia in the country, five major surveys NFHS 2 and 3,[6,7] DLHS 2,[8] ICMR Micronutrient Survey[9] and Micronutrient Survey conducted by NNMB[10] were undertaken to estimate prevalence of anaemia in the country. All these showed that over 70% of preschool children were anaemic. NNMB,[10] DLHS[8] and ICMR[6,7] surveys showed that over 70% of pregnant women and adolescent girls in the country were anaemic. Anaemia begins in childhood, worsens during adolescence in girls and gets aggravated during

pregnancy. Data from DLHS[8] showed that prevalence of moderate and severe anaemia was high even among educated and higher income groups. Prevalence of anaemia is high in all the States, though there are considerable variations between different states in prevalence of moderate and severe anaemia.[8]

Rural Status

According to NFHS-2 survey rural women population has higher prevalence rate of anaemia (53.9%) as compared to urban women population (51.5%).[6] NFHS-3 showed 51.5% prevalence of anaemia in urban women and 58.2% in rural women.[7]

Literacy status

NFHS-2 study provides information that anaemia is more prevalent in illiterate women (55.8%), while it is only 40.8% prevalent in women who have completed their high school studies.[6]

Socioeconomic status

The disease has been reported to be more prevalent in low socioeconomic status women (60.2%) in survey reported by NHFS-2.[6] while high socio-economical class women had 41.9% prevalence. A study in 2004 reports the prevalence of anaemia in women from low socio-economic status is 63.2% and that of 38.5% in higher socio-economical status women.[23]

Factors responsible for high prevalence of anaemia

The risk of IDA is particularly high in women who begin gestation with depleted or low body iron stores, a situation common in Africa and most third world

countries, where high parity and short intervals between children are often found.[24] Also, iron requirements during pregnancy are not easily satisfied by dietary intakes, which generally provide poor iron bioavailability.[25,26]

Studies carried out in India and elsewhere have shown that iron deficiency is the major cause of anaemia followed by folate deficiency. In recent years, the contribution of B12 deficiency has been highlighted.[27] In India, the prevalence of anaemia is high because of (*i*) low dietary intake, poor iron (less than 20 mg /day) and folic acid intake (less than 70 mg/day); (*ii*) poor bioavailability of iron (3-4% only) in phytate and fibre-rich Indian diet; and (*iii*) chronic blood loss due to infection such as malaria and hookworm infestations.[9,10]

Hookworm infection has long been recognized among the major causes of anaemia in poor communities,[28] but understanding of the benefits of the management of hookworm infection in pregnancy has lagged behind the other major causes of maternal anaemia. An epidemiological study in 1995 highlighted the paradox presented to public health workers that an estimated one-third of all pregnant women in developing countries were infected with hookworm and yet, in the absence of safety data, the appropriate advice was to avoid the use of anthelmintics in pregnancy.[29]

Furthermore, the lack of an acceptable intervention constrained the development of evidence-based understanding of the impact of hookworm infection on maternal anaemia.[30]

These issues were addressed directly by a study[31] which analysed the safety profile of some 20 years of mebendazole use in antenatal clinics in Sri Lanka. In

2002, WHO published new guidance indicating that pregnant women should be treated for hookworm infection, ideally after the first trimester.[32] This immediately provided the opportunity for improved service delivery, and also encouraged studies to assess the contribution of hookworm to anaemia in pregnancy and the impact of treatment, some of which have been undertaken since 2002. These provide a rich new source of data to help inform public health decision making, and in this paper we present a systematic review of hookworm as a risk factor for anaemia among pregnant women.[33]

Data from NNMB surveys[34] showed that iron and folic acid intake in the country in all the age groups was very low. There has not been any increase in iron intake over the last three decades in any group. The apparent reduction in iron intake in the NNMB surveys 2000-0115 and beyond was due to the finding that only 50% of the iron in Indian diets is absorbable.

Poor iron stores at birth,[35] low iron content of breast milk and low dietary iron intake through infancy and childhood results in high prevalence of anaemia in childhood.[8,36] Anaemia gets aggravated by increased requirements during adolescence and during pregnancy.[8] Assuming that the absorption of iron is 8% in pregnant women, their average dietary intake will meet only 30-45% of the requirement. The low dietary intake of iron, folic acid and food stuffs that promote iron absorption, coupled with poor bioavailability of iron are the major factor responsible for very high prevalence of anaemia in the country.

Anaemia and iron deficiency in the mother are not associated with significant degree of anaemia in the children during neonatal period. However, iron stores in

these neonates are low, iron content in breast milk in anaemic women is low and because of these factors substantial proportion of infants become anaemic by six months.[35] Thus maternal iron deficiency and anaemia render the offspring vulnerable for developing iron deficiency and anaemia right from infancy. Poor iron content of complementary food and family food consumed by the young child results in further increase in prevalence of anaemia in childhood.[36] With the onset of menstruation and associated blood loss, there is a further rise in prevalence and severity of anaemia in adolescent girls.[8] Early marriage and adolescent pregnancy aggravate anaemia6 and result in poor iron stores in the offspring. It is obvious that there is an intergenerational self perpetuating vicious cycle of anaemia in Indian population.

Immune status of anaemic pregnant women

In pregnancy, profound changes occur in several laboratory parameters used for the assessment of immune status. Studies undertaken by the National Institute of Nutrition, Hyderabad, showed that there was a fall in T and B cell count with fall in haemoglobin levels below 11 g/dl. The fall in T and B cells was statistically significant in women with haemoglobin levels below 8 g/dl. Immunoglobin levels showed a progressive rise with decreasing Hb levels. The changes in T and B cells and immunoglobulin were reversed within 6-12 wk by parenteral iron therapy and improvement in haemoglobin levels, indicating that these alterations are due to anaemia *per se* and not due to co-existent undernutrition.[37,38]

Parasitic diseases, including helminth infections and *P. falciparum*, have long been recognized as important contributors to anaemia in endemic countries.[39]

The effects of infection with a single helminth species on the risk of anaemia are also well documented, with risk correlated to infection intensity.[40] Hookworm causes iron deficiency anaemia through the process of intestinal blood loss and through nitric oxide (NO) release.[28,41]

Soil transmitted helminths, especially hook worm infection is well known to cause anaemia. Data from the early 1990s suggested that 44 million of the developing world's 124 million pregnant women harbored hookworm infection;[42] with 7.5 million in sub–Saharan Africa alone. Hookworm infection is considered a major health threat to adolescent girls and women of reproductive age, with adverse effects on the outcome of pregnancy.[43]

Malaria due to *P. falciparum* also clearly contributes to anaemia throughout life and specifically during pregnancy. It is estimated that in sub-Saharan Africa 23 million pregnant women are exposed to malaria infection annually and approximately 400,000 pregnant women develop moderate or severe anaemia (haemoglobin < 80 g/L or hematocrit < 0.25) each year in sub-Saharan Africa as a result of malaria infection.[44]

The mechanisms by which malaria and intestinal helminth infections cause anaemia differ, it is possible that their impact on anaemia are additive[45] and could exacerbate adverse birth outcomes.[46]

In India, investigations carried out among pregnant women in villages near Hyderabad indicated that the prevalence of morbidity due to infections was doubled in women with haemoglobin levels below 8.0 g/dl.[4] Data from both the developed and the developing countries have documented the association between

asymptomatic bacteriuria and anaemia, often refractory to treatment, poor intrauterine growth, prematurity and low birth weight. It is possible that immunosuppression in anaemic women renders them more susceptible to infection which might be and increased morbidity due to infection, might be one of the factor responsible for the adverse effect of anaemia on the course and outcome of pregnancy.[37,38]

Iron Metabolism

The balance of iron metabolism in healthy individuals predominantly reflects three variables: nutritional intake, iron loss, and current demand. The nutritional iron intake relates to the amount of digested iron in food and the ability to absorb iron from the digestive tract. The amount of iron absorbed depends largely on the presence or absence of pathology of the gastrointestinal tract or a comorbidity (such as chronic inflammatory diseases) that may result in expression of the iron regulatory proteins and a peptide called hepcidin, which ultimately blocks iron absorption. The main source of iron in humans comes from the destruction of erythrocytes by macrophages of the reticuloendothelial system including the spleen or in other words, a recycled internal iron supply.[47]

Recent studies have shown how the human body up and down regulates iron absorption in response to changing iron status via intestinal and hepatic proteins.[47]

Iron Metabolism in Pregnancy

During pregnancy, fetal hepcidin controls the placental transfer of iron from maternal plasma to the fetal circulation. When hepcidin concentrations are low, iron enters blood plasma at a high rate. When hepcidin concentrations are high,

ferroportin is internalized, and iron is trapped in enterocytes, macrophages, and hepatocytes. The daily requirement of external iron remains as little as between 1 to 8 mg daily. However, more external iron is required to balance increased demand for iron especially with physiological requirements during growth, pregnancy, and lactation. This significant increased demand for iron is required to develop the fetus and placenta in addition to support mother's blood volume. Furthermore, pregnant women are subject to iron loss during and after delivery. The total iron loss associated with pregnancy and lactation is approximately 1000 mg. Therefore the recommended daily dietary allowance for iron in pregnancy is 27 mg instead of 8 mg in the adult non-pregnant population. Lactation requires a daily dietary allowance of 10 mg.[47]

Diagnosis

Full blood count and MCV value allowing the diagnosis of microcytic anaemia is considered a good screening tool for IDA. However, in areas of the world where haemoglobinopathies are prevalent and these may be associated with microcytosis, iron studies, in particular ferritin level remains the surrogate marker for IDA. According to the ferritin level, iron deficiency can be classified as severe ID when the ferritin level is <30 μg/L or mild-moderate ID if ferritin <100 μg/L and >30 μg/L (there is a wide normal range between 20 and 464 and is laboratory and method specific).[47]

In cases of elevated ferritin >100 μg/L with a concurrent anaemia, a reactive common cause such as infection should be excluded and other causes of anaemia should be examined accordingly. Other complementary tests in iron studies such as

serum iron, iron binding capacity, and transferrin saturation are helpful in confirming the diagnosis of IDA.[47]

Maternal consequences of anaemia

Mild anaemia

Women with mild anaemia in pregnancy have decreased work capacity. They may be unable to earn their livelihood if the work involves manual labour. However, women with chronic mild anaemia may go through pregnancy and labour without any adverse consequences, because they are well compensated.[4]

Moderate anaemia

Women with moderate anaemia have substantial reduction in work capacity and may find it difficult to cope with household chores and child care. Available data from India and elsewhere indicate that maternal morbidity rates are higher in women with Hb below 8gm/dl.[48] They are more susceptible to infections and recovery from infections may be prolonged. Premature births are more common in women with moderate anaemia. They deliver infants with lower birth weight and perinatal mortality is higher in these babies.[48] They may not be able to bear blood loss prior to or during labour and may succumb to infections more readily. Substantial proportion of maternal deaths due to antepartum and post-partum haemorrhage, pregnancy induced hypertension and sepsis occur in women with moderate anaemia.

Severe anaemia

Three distinct stages of severe anaemia have been recognized - compensated, decompensated, and that associated with circulatory failure. Cardiac decompensation usually occurs when Hb falls below 5.0 g/dl. The cardiac output is raised even at rest, the stroke volume is larger and the heart rate is increased. Palpitation and breathlessness even at rest are symptoms of these changes. These compensatory mechanisms are inadequate to deal with the decrease in Hb levels. Oxygen lack results in anaerobic metabolism and lactic acid accumulation occurs. Eventually circulatory failure occurs further restricting work output. Untreated, it leads to pulmonary oedema and death. When Hb is <5 g/dl and packed cell volume (PCV) below 14, cardiac failure is seen in a third of cases.[49]

A blood loss of even 200 ml in the third stage produces shock and death in these women. Even today women in the remote rural areas in India reach to the hospital only at this late decompensated stage. Maternal mortality rates show a steep increase when maternal Hb levels fall below 5.0 g/dl. Anaemia directly causes 20 per cent of maternal deaths in India and indirectly accounts for another 20 per cent of maternal deaths.[50]

Foetal consequences of anaemia

Studies to define the effect of maternal anaemia on the foetus indicate that different types of decompensation occur with varying degrees of anaemia. Most of the studies suggest that a fall in maternal haemoglobin below 11.0 g/d1 is associated with a significant rise in perinatal mortality rate.[38,39,51]

There is usually a 2 to 3-fold increase in perinatal mortality rate when maternal haemoglobin levels fall below 8.0 g/d1 and 8-10 fold increase when

maternal haemoglobin levels fall below 5.0 g/dl21.[52] A significant fall in birth weight due to increase in prematurity rate and intrauterine growth retardation has been reported when maternal haemoglobin levels were below 8.0 g/d1.[51,52,53]

Factors responsible for the adverse obstetric outcome

Investigations undertaken to determine the factors responsible for the adverse maternal and perinatal outcome seen in association with anaemia indicated that anaemia per se might be responsible for some of the obstetric adverse effects.[38,39,48-50,53,54] However, prevalence of several maternal risk factors which are associated with low birth weight, increased perinatal, maternal morbidity and mortality, such as pregnancy induced hypertension (PIH) and antepartum haemorrhage (APH) are higher among anaemic women.[48] It is, therefore, possible that coexisting obstetric problems contribute, at least in part, to the adverse obstetric outcome reported among anaemic women. Anaemic women should, therefore, be treated as a high risk obstetric group.

Immune depression due to anaemia and consequent increased morbidity due to infection, especially urinary tract infection, might be one of the factors responsible for low birth weight babies in anaemic women. Screening for, and effectively treating infections in anaemic women might therefore result in improved foetal and maternal prognosis.[39]

In the habitual cereal and pulse based diets consumed by Indian women, there is an almost linear correlation between calorie and iron intake.[38] Women with haemoglobin levels below 8.0 g/dl weigh less than their non-anaemic counterparts from similar income groups.[39,46] These data suggest that anaemia might be one

manifestation of overall maternal dietary inadequacy and consequent undernutrition.[39] It is possible that supplementary feeding programmes aimed at improvement of maternal dietary intake might result in some improvement in maternal haemoglobin status.

Poverty, ignorance, non availability and/or failure to utilize available medical facilities have been shown to be associated with maternal anaemia on the one hand and maternal and perinatal morbidity and mortality on the other, though the association is not causal. Health education to improve the utilization of available facilities and improvement in the health care delivery system to cater to the needy, right at their doorsteps might thus go along way in reducing adverse obstetric outcome associated with maternal anaemia.

Prevention and management of anaemia in pregnancy

In view of the high prevalence of anaemia in pregnancy and serious adverse consequences in both mother and baby, management of anaemia in pregnancy was accorded a very high priority both in obstetric and public health practice. Mandatory monthly screening for anaemia became the 'routine' in all antenatal clinics. Skilled management of severe grades of anaemia detected late in pregnancy, through blood transfusion and parenteral iron therapy became the hallmark of good obstetric practice and resulted in maternal and perinatal salvage rates in hospitals. However, it became obvious that unless effective steps were taken to reduce the prevalence of anaemia, further reduction in morbidity and mortality rates could not be achieved.[4]

Iron deficiency is potentially both preventable and treatable. Effective management strategies that allow women to replenish iron stores, both antenatal or

during labour, restore haemoglobin values and are likely to enhance the health of the mother and infant.[55]

Iron has been used to treat anaemia for more than 300 years. However, it was not until the 19th century when Pierre Blaud introduced ferrous sulfate that it became the standard treatment for IDA.[57]

Treatment with oral iron supplements is simple, inexpensive and a relatively effective way of treating iron deficiency conditions. Ferrous iron salts (sulfate, fumarate, succinate and gluconate) are the most commonly used oral iron preparations; they are similar in regards to pharmacodynamic and pharmacokinetic properties as well as to the rate of adverse events.[57]

Because of the high rate of gastrointestinal adverse effects (35% to 59%) with ferrous sulfate, new compounds containing either the ferric or ferrous salt forms have been developed as different preparations (amino-acid chelates, carbonyl iron, iron III polymaltose complex [IPC], extended-release products) and approved for clinical use.[57]

For the treatment of IDA in adults, the recommended daily dose of elemental iron is in the range of 150 to 200 mg/day; for children the dose is 3-6 mg iron/Kg body weight/day. From a practical point of view, doses of 100-200 mg/day of elemental iron are a compromise between the optimum Hb increase and body iron replenishment with minimal side effects.[57] However, some studies have shown that smaller daily doses of elemental iron may be adequate to prevent iron deficiency and can also correct IDA without producing substantial side effects.[58,59]

Successful overall management of the patient with IDA must include attempts to identify and treat, if possible, the underlying cause(s) of the iron deficiency. Very few patients will fail to respond to oral iron salts provided significant doses can be tolerated.[57]

Overall, for many decades the mainstay treatment of IDA has been oral iron and red blood cell (RBC) transfusions. However, oral iron supplementation can lead to significant side effects resulting in non-compliance in many patients[60] and the risks for RBC transfusion are well described and should be avoided whenever possible.[61] Intravenous iron formulations offer an alternative approach in the presence of moderate or severe anaemia, intolerance of or non-adherence to oral iron and malabsorption states.[62] Intravenous iron is less commonly used as fear of anaphylaxis with iron dextran formulations, and long infusion time with iron polymaltose, have led to reluctance amongst clinicians.[63] The development of dextran free parenteral iron formulations with an improved safety profile, and a more rapid delivery time suggests that intravenous iron should be considered as a mainstay treatment for moderate to severe IDA.[47]

Iron Sucrose and Ferric Carboxymaltose are dextran free intravenous iron alternatives. When compared to oral iron in pregnancy iron sucrose is superior with respect to the rate of both haemoglobin increase and iron store replenishment, combined with a good safety profile.[62,64,65]

Serious adverse effects are rare with iron sucrose, however minor side effects occur in up to 18% of patients which may in part be attributed to its non-physiological physical properties (high pH and high osmolarity). Ferric

carboxymaltose is a newer dextran-free iron formulation with a near neutral pH, physiological osmolarity and increased bioavailability which allows for single dose, short 15 minute infusion time and higher dosing (up to 1000 mg).[66] These properties make ferric carboxymaltose an attractive alternative to iron sucrose in terms of risk profile, efficacy, patient comfort and convenience, staff and institutional resource utilization.

Iron sucrose can be safety administered as a 15-30 minute infusion in doses of 200-300 mg; the maximum weekly dose should not exceed 600 mg. If higher-than-recommended doses are not infused, adverse effects are rarely observed.[57]

An ideal preparation for intravenous iron replacement therapy should balance effectiveness and safety. Compounds that release iron rapidly tend to cause toxicity, while large molecules can induce antibody formation and cause anaphylactic reactions. There is therefore a need for an intravenous iron preparation that delivers appropriate amounts of iron in a readily available form but with minimal side effects and thus with an excellent safety profile. In this paper, a review is given on the chemistry, pharmacology, and toxicology of ferric carboxymaltose (FCM, Ferinject), a stable and robust complex formulated as a colloidal solution with a physiological pH.[67]

The complex is gradually taken up mainly from the hepatic reticulo-endothelial system (RES), followed by effective delivery of iron to the endogeneous transport system for the haem synthesis in new erythrocytes, as shown in studies on the pharmacodynamics and pharmacokinetics with radio-labelled FCM. Studies with radio-labelled FCM also demonstrated a barrier function of the placenta and a low

transfer of iron into the milk of lactating rats. Safety pharmacology studies indicated a favourable profile with regard to cardiovascular, central nervous, respiratory, and renal toxicity. A high maximum non-lethal dose was demonstrated in the single-dose toxicity studies. Furthermore, based on the No-Observed-Adverse-Effect-Levels (NOAELs) found in repeated-dose toxicity studies and on the cumulative doses administered, FCM has good safety margins.[57]

Reproductive and developmental toxicity studies did not reveal any direct or indirect harmful effects. No genotoxic potential was found in in vitro or in vivo studies. Moreover, antigenicity studies showed no cross-reactivity of FMC with anti-dextran antibodies and also suggested that FCM does not possess sensitizing potential. Lastly, no evidence of irritation was found in local tolerance studies with FCM. This excellent toxicity profile and the high effectiveness of FCM allow the administration of high doses as a single infusion or bolus injection, which will enhance the cost-effectiveness and convenience of iron replacement therapy. In conclusion, FCM has many of the characteristics of an ideal intravenous iron preparation.[57]

A retrospective cohort study was performed in Bern, Switzerland, from 2008, on 206 anaemic pregnant women who were treated with either iron carboxymaltose or iron sucrose. The occurrence of drug related adverse effects was low and mostly mild in both the groups. It was about 7.8% for iron carboxymaltose group and 10.7% for iron sucrose group. Most importantly the mean rise of hemoglobin value in the study was found as 15.4 gm/dl for iron carboxymaltose group and 11.7gm/dl for the group who received treatment with iron sucrose.[68]

In a meta-analysis done in 2011, they evaluated the efficacy and safety of intravenous ferric carboxymaltose. It states that intravenous ferric carboxymaltose improved mean haemoglobin, serum ferritin, and transferrin saturation levels. The mean rise in haemoglobin at the end of the study was 4.8 g/l, serum ferritin increased by 163 μg/L and transferrin saturation increased by 5.3% .The study states that ferric carboxymaltose was significantly better than its comparator in achievement of target haemoglobin increase. Serious adverse events and deaths were similar in incidence in ferric carboxymaltose and comparators; rates of constipation, diarrhoea, and nausea or vomiting were lower than with oral iron.[69]

In another 2 randomised controlled clinical trials; one in 2007, Russia and another in 2008, Newburgh, Indiana. Both the studies concluded that iron carboxymaltose was as effective as oral iron sulfate in changing haemoglobin, despite the much shorter treatment period (2 weeks vs 12 weeks). Ferritin levels were significantly higher. Except for injection site burning, iron carboxymaltose was better tolerated than ferrous sulfate, mainly concerning gastrointestinal side effects. There were no safety concerns identified in breast-fed infants.[70,71]

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METHODOLOGY

The present study was conducted in the department of Obstetrics and Gynaecology, KLES Dr Prabhakar Kore Hospital and Medical Research Centre, Belgaum during the period of January 2013 to July 2014.

Study Design

The study design was open labeled randomized controlled trial.

Study period and duration

The present study was conducted from January 2013 to July 2014.

Place

This study was conducted at Department of Obstetrics and Gynaecology, KLES Dr Prabhakar Kore Hospital and Medical Research Centre, Belgaum a teaching hospital attached to Jawaharlal Nehru Medical College, Belgaum.

Source of data

All antenatal women admitted at Department of Obstetrics and Gynaecology, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum were studied.

Sample size

A sample size of 305 pregnant women was planned. Based on the calculation the effect sample size was 230 however, 305 women fulfilled selection criteria hence enrolled.

Sampling procedure

Earlier study has mentioned mean and SD of hemoglobin with the treatment of iron carboxymaltose and iron sucrose are mentioned as 97.4 ± 9.9 (gm/L) and 94.5 ± 4.9 (gm/L) respectively.[76] The level of haemoglobin at the end of the treatment is an important parameter of the study, hence these levels of haemoglobin mentioned in the above study were used to calculate the minimum sample size Using the formula;

$$n = \frac{(Z_\alpha + Z_\beta)^2 \times 2s^2}{(X_1 - X_2)^2}$$

≈ 114 in each group≈ 115*

Where: $X_1 = 97.4$, $X_2 = 94.5$

$S_1 = 9.9$, $S_2 = 4.9$,

$2S^2 = S_1^2 + S_2^2$

Z_α -1.96 for 5% level

Z_β -0.84 for 80% power of the test.

Hence sample size was taken as 115 in each group totaling to a sum of 230 cases.

Selection criteria

Inclusion

- Pregnant women whose haemoglobin is in the range of 7 to 11 gm/dL.
- Women between 16 to 35 weeks period of gestation.

Exclusion

- Women not willing to participate.
- Other causes of anaemia.
- Serious medical complications.
- Women who have a history or known allergic to parentral iron infusion.

The study protocol comprised of the following activities:

1. Screening
2. Consent
3. Measurement of Pre-treatment Hemoglobin and calculation of total required dose of iron.
4. Randomization
5. Administration of the Intervention
6. Measurement of post-treatment (4 weeks) Hemoglobin

Ethical clearance

The study was approved by the Institutional Ethics Committee of Jawaharlal Nehru Medical College, Belgaum.

Consent form

Pregnant women fulfilling selection criteria at Department of Obstetrics and Gynaecology at KLES Dr Prabhakar Kore Hospital and Medical Research Centre, Belgaum were briefed about the nature of the study, details of the treatment and a written informed consent was obtained (Annexure I).

Data collection

Demographic data like age, education, qualification, socio economic status was obtained and recorded on predesigned and pretested proforma. Patients were interviewed for obstetric history. The study investigators examined the participants for their general health and obstetric parameters. The weight, height of the participants was recorded using standard methodology (Annexure II).

Randomisation

Random allocation sequence generation

Randomisation was done by computer generated random numbers assigning numbers to both groups.

Random allocation implementation

The participant was assigned to iron sucrose, or iron carboxymaltose group as per the random sequence list in masked fashion.

Intervention

The participants were subjected to iron transfusion, iron sucrose or iron ferric carboxymaltose according to randomisation, haemoglobin estimation is done and the iron deficit was calculated according to formula:

Deficit = (11-Hemoglobin of the patient) x 2.4 x Weight + 500 (storage)

Group S – Iron sucrose

Iron sucrose was given in a dose of 200 mg intravenously in 200 ml normal saline over a period of 15-20 min on alternate days until the required total dose was administered; not exceeding the maximum dose of 1000 mg/week. All the doses was given in the ward where equipment for cardiopulmonary resuscitation was available. Patients were observed for side effects or anaphylactic reactions. Any minor or major side effects were documented. Haemoglobin test was repeated at the end of 4 weeks interval.

Group C – Ferric Carboxymaltose

Ferric Carboxymaltose was given as per the total required dose in normal saline infusion as follows:

Iv drip infusion : Dilute in 0.9% sodium chloride

100 to 200 mg: 50 ml NS

200 to 500 mg : 100 ml NS - 6 min duration

500 to 1000mg : 250 ml NS - 15 min duration

Not exceeding the maximum dose of 1000 mg / day/ week. All the doses were given in the ward where equipment for cardiopulmonary resuscitation was

available. Patients were observed for side effects or anaphylactic reactions. Any minor or major side effects were documented. Haemoglobin test was repeated at the end of 4 weeks interval.

Follow up

The participants were observed during transfusion and immediately for any adverse reaction immediate or late. They were followed up after four weeks, for haemoglobin estimation to note the rise in haemoglobin values. The requirement for blood transfusion if any, were noted.

Analysis of hemoglobin levels

The samples were sent to Pathology laboratory in KLES DR Prabhakar Kore Hospital and Medical Research Centre, Belgaum the reports were collected and entered into the data base. The baseline hemoglobin was assessed before the treatment and rise on hemoglobin was assessed four weeks after the treatment.

Statistical analysis

The categorical data was expressed in terms of frequencies and percentages while continuous data was expressed as mean ± standard deviation (SD). The two groups were compared using chi-square test for categorical data and independent sample ‘t’ test was used to compare the means of different parameters. A ‘p’ value of less than or equal to 0.050 was considered as statistically significant.

RESULTS

The present study was conducted in the department of Obstetrics and Gynaecology, KLES Dr Prabhakar Kore Hospital and Medical Research Centre, Belgaum during the period of January 2013 to July 2014. The minimum sample size was considered as 230 patients divided into two groups of 115 each. However a total of 305 women satisfied selection criteria and were included in the study. These women were randomized into two groups as below.

- Group C (n=158): Received iron carboxymaltose transfusion.
- Group S (n=147): Received iron sucrose transfusion.

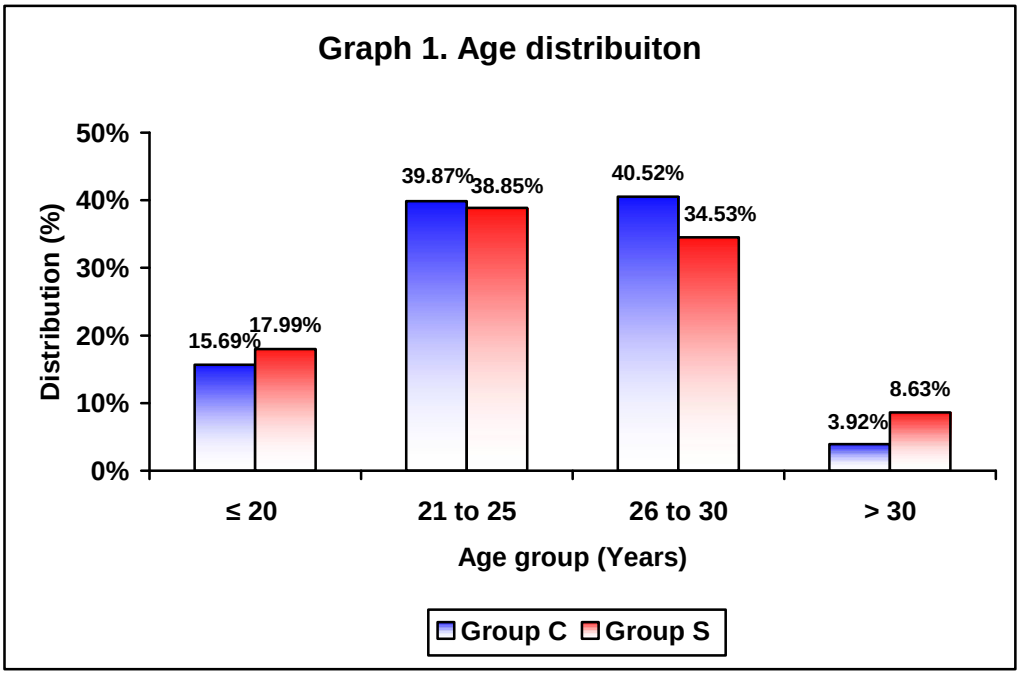
Of the 158 women included in group C, five were lost to follow up and in group S, of the 147 women seven lost to follow up while one woman delivered. Hence the outcome data was available for 153 women in group C and 139 women in group S.

The data was analysed and the final results and observations were tabulated as below.

Table 1. Age distribution

Age group (Years)	Group C (n=153)		Group S (n=139)	
	Number	**Percentage**	**Number**	**Percentage**
≤ 20	24	15.69	25	17.99
21 to 25	61	39.87	54	38.85
26 to 30	62	40.52	48	34.53
> 30	6	3.92	12	8.63
Total	**153**	**100.00**	**139**	**100.00**

p = 0.312



In the present study most of the women (40.52%) were aged between 26 to 30 years in group C while in group S most of the women (38.85%) had age between 21 to 25 years and this difference was statistically not significant (p=0.312).

Table 2. Mean age

	Group C (n=153)		Group S (n=139)		p value
	Mean	**SD**	**Mean**	**SD**	
Mean age (Years)	25.33	3.53	24.85	4.18	0.082

In this study the mean of the study population in group C and S was comparable (25.33 ± 3.53 vs 24.85 ± 4.18 years; p=0.082)

Table 3. Occupation

Occupation	**Group C (n=153)**		**Group S (n=139)**	
	Number	**Percentage**	**Number**	**Percentage**
Housewife	96	62.75	79	56.83
Working	57	37.25	60	43.17
Total	**153**	**100.00**	**139**	**100.00**

p = 0.303

In the present study most of the women in group C and S were housewives (62.75% vs 56.83%; p=0.303).

Table 4. Education

Education	Group C (n=153)		Group S (n=139)	
	Number	**Percentage**	**Number**	**Percentage**
Illiterate	21	13.73	8	5.76
Read and Write	74	48.37	64	46.04
Primary	48	31.37	48	34.53
Secondary	8	5.23	13	9.35
Graduate	2	1.31	6	4.32
Total	**153**	**100.00**	**139**	**100.00**

p = 0.059

The educational status of the study population in group C and S was comparable (p=0.059).

Table 5. Socio economic status

SES	Group C (n=153)		Group S (n=139)	
	Number	**Percentage**	**Number**	**Percentage**
Class 1	34	22.22	36	25.90
Class 2	44	28.76	51	36.69
Class 3	68	44.44	47	33.81
Class 4	7	4.58	5	3.60
Total	**153**	**100.00**	**139**	**100.00**

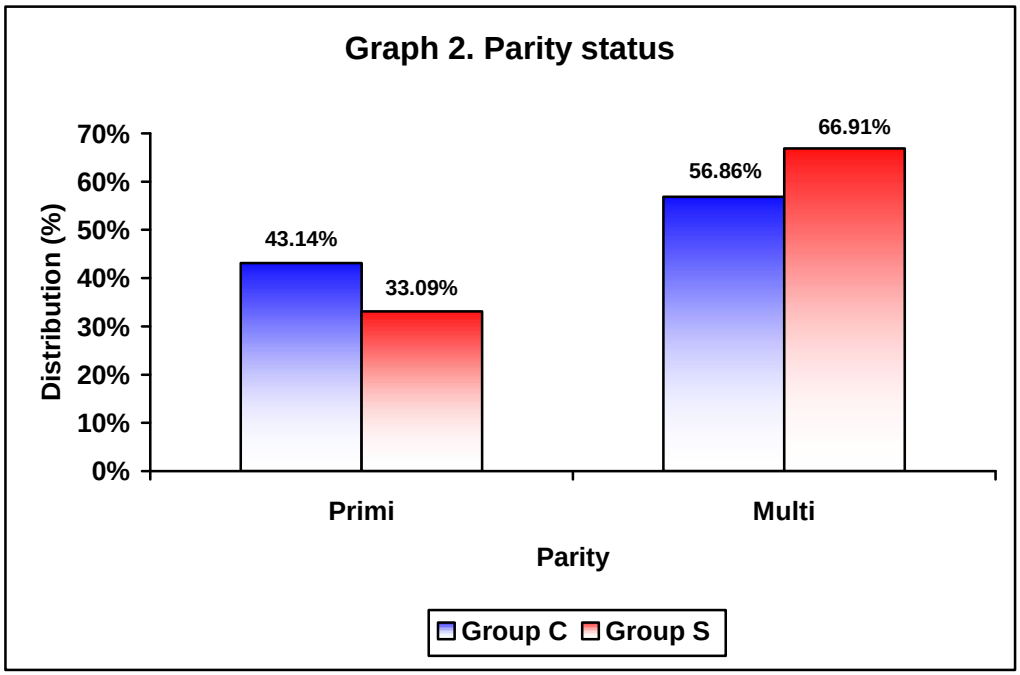
p = 0.253

In this study 44.44% of the women reported class III socio economic status in group C compared to 33.81% in group S and this difference was statistically not significant (p=0.253)

Table 6. Parity status

Parity	Group C (n=153)		Group S (n=139)	
	Number	**Percentage**	**Number**	**Percentage**
Primi	66	43.14	46	33.09
Multi	87	56.86	93	66.91
Total	**153**	**100.00**	**139**	**100.00**

p = 0.078

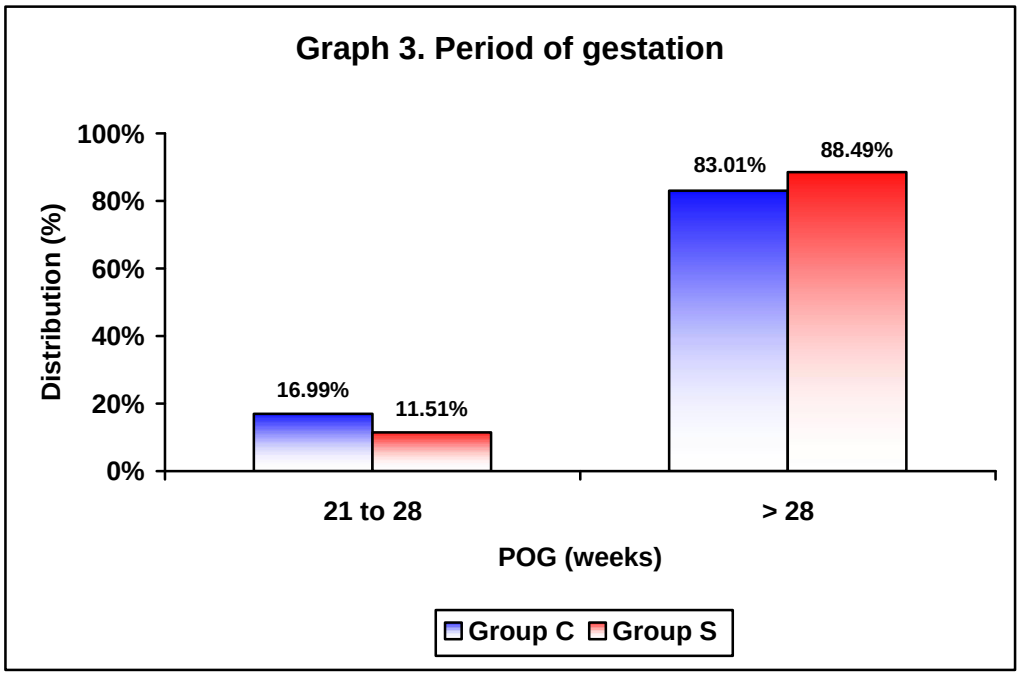


In this study most of the women had multi parity in group C (56.86%) and group S (66.91%). However the parity status of study population was comparable in both the group (p=0.078)

Table 7. Period of gestation

POG (weeks)	Group C (n=153)		Group S (n=139)	
	Number	**Percentage**	**Number**	**Percentage**
21 to 28	26	16.99	16	11.51
> 28	127	83.01	123	88.49
Total	**153**	**100.00**	**139**	**100.00**

p = 0.182



In the present study majority of the women in group C (83.01%) and group S (88.49%) presented with more than 28 weeks (p=0.182).

Table 8. Mean period of gestation

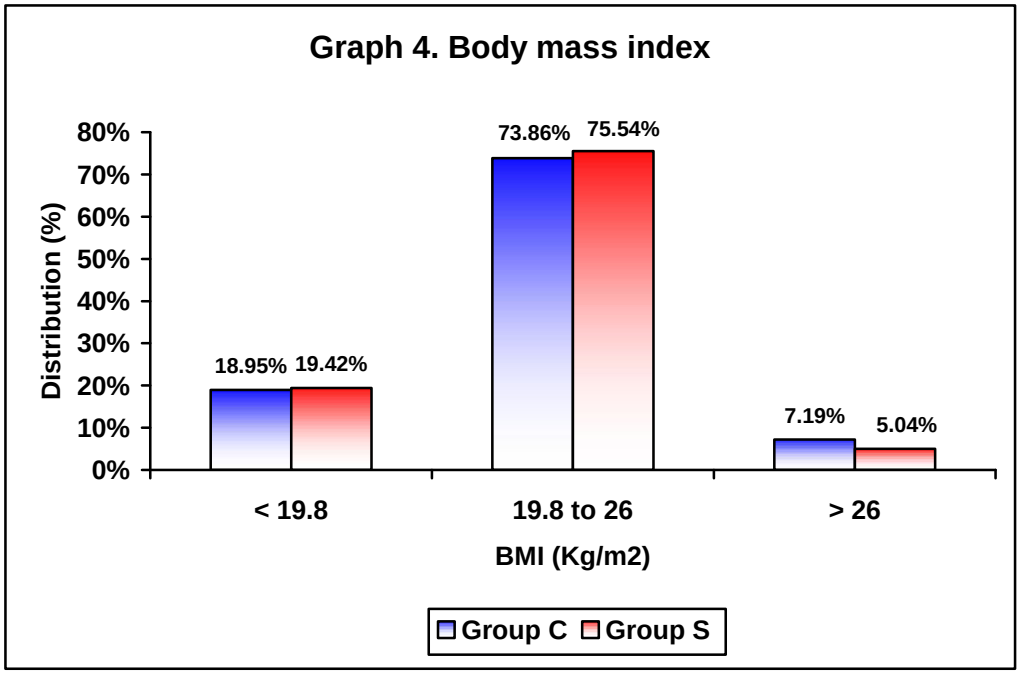
	Group C (n=153)		Group S (n=139)		p value
	Mean	**SD**	**Mean**	**SD**	
Period of gestation (weeks)	30.61	4.05	30.77	3.28	0.706

In the present study mean period of gestation in group C was 30.61 ± 4.05 weeks and in group S the same was noted as 30.77 ± 3.28 weeks (p=0.706).

Table 9. Body mass index

BMI (Kg/m^2)	Group C (n=153)		Group S (n=139)	
	Number	**Percentage**	**Number**	**Percentage**
< 19.8	29	18.95	27	19.42
19.8 to 26	113	73.86	105	75.54
> 26	11	7.19	7	5.04
Total	**153**	**100.00**	**139**	**100.00**

p = 0.747



In the present study majority of the women had BMI between 19.8 to 26 Kg/m^2 in group C (73.86%) and group S (75.54%). However no statistically significant difference was noted between the two groups (p=0.747).

Table 10. Mean BMI

	Group C (n=153)		Group S (n=139)		p value
	Mean	**SD**	**Mean**	**SD**	
BMI (Kg/m^2)	21.92	2.69	21.69	2.56	0.464

In this study the mean BMI in group C and S was comparable (21.92 ± 2.69 vs 21.69 ± 2.56 Kg/m^2; p=0.464)

Table 11. Comparison of vitals

Variables	Group C (n=153)		Group S (n=139)		p value
	Mean	SD	Mean	SD	
Pulse rate (/minute)	79.31	4.38	79.84	4.33	0.301
Systolic BP (mmHg)	113.40	6.32	113.87	6.11	0.517
Diastolic BP (mm Hg)	76.22	5.26	75.78	5.17	0.474

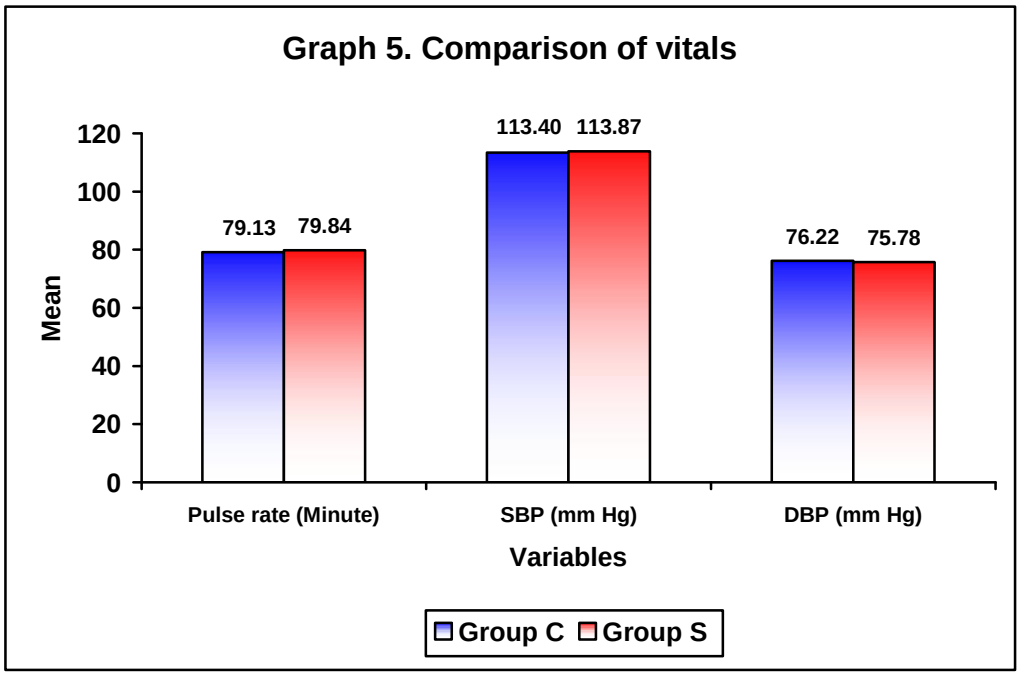
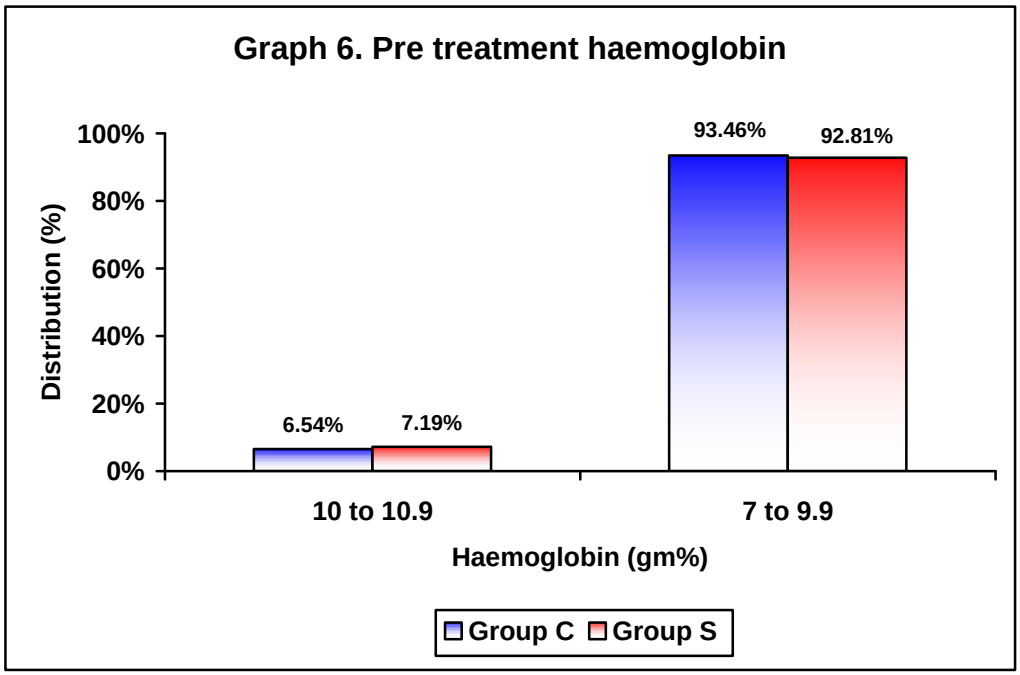


Table 11 and graph 5 shows comparison of vitals. It was observed that, vitals were comparable in both the groups (p>0.050).

Table 12. Pre treatment haemoglobin

Haemoglobin (gm%)	Group C (n=153)		Group S (n=139)	
	Number	**Percentage**	**Number**	**Percentage**
10 to 10.9	10	6.54	10	7.19
7 to 9.9	143	93.46	129	92.81
Total	**153**	**100.00**	**139**	**100.00**

p = 0.824



In this study majority of the women in group C (93.46%) and group S (92.81%) had haemoglobin levels between 7.0 to 9.9 (p=0.824).

Table 13. Mean Haemoglobin - Pre treatment

	Group C (n=153)		Group S (n=139)		p value
	Mean	**SD**	**Mean**	**SD**	
Hb (gm%)	8.70	0.84	8.82	0.84	0.205

In this study pre-treatment mean haemoglobin levels were comparable in both the groups (8.70 ± 0.84 vs 8.82 ± 0.84 gm%; p=0.205)

Table 14. Mean iron requirement and doses

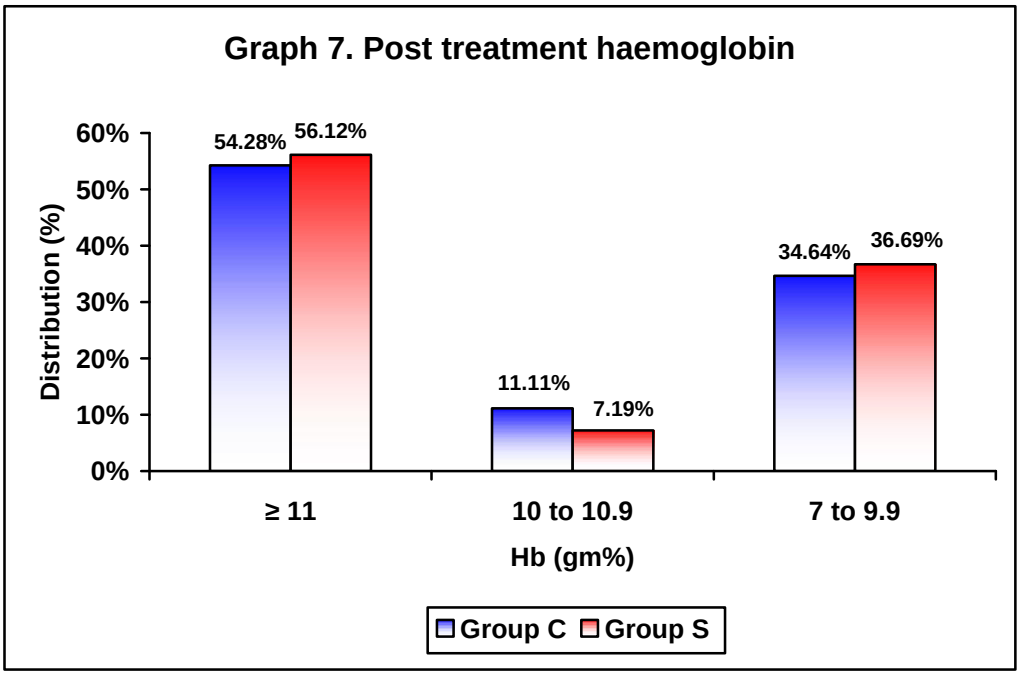
Variable	Group C (n=153)		Group S (n=139)		p value
	Mean	**SD**	**Mean**	**SD**	
Iron requirement	809.19	115.77	783.35	112.59	0.054
Doses	797.78	123.07	776.47	137.37	0.166

The mean iron requirement and doses in group C and group S are as shown in table 14. The mean iron requirement in group C was 809.19 ± 115.77 compared to 783.35 ± 112.59 and this difference was statistically not significant (p=0.054) However, the doses in group C and S were comparable (p=0.166).

Table 15. Post treatment haemoglobin

Hb (gm%)	Group C (n=153)		Group S (n=139)	
	Number	**Percentage**	**Number**	**Percentage**
≥ 11	83	54.25	78	56.12
10 to 10.9	17	11.11	10	7.19
7 to 9.9	53	34.64	51	36.69
Total	**153**	**100.00**	**139**	**100.00**

p = 0.512



In this study post treatment haemoglobin levels were found to be 11 or more in 54.25% of the women in group C and 56.12% in group S. However this difference was statistically not significant (p=0.512).

Table 16. Mean Haemoglobin - Post treatment

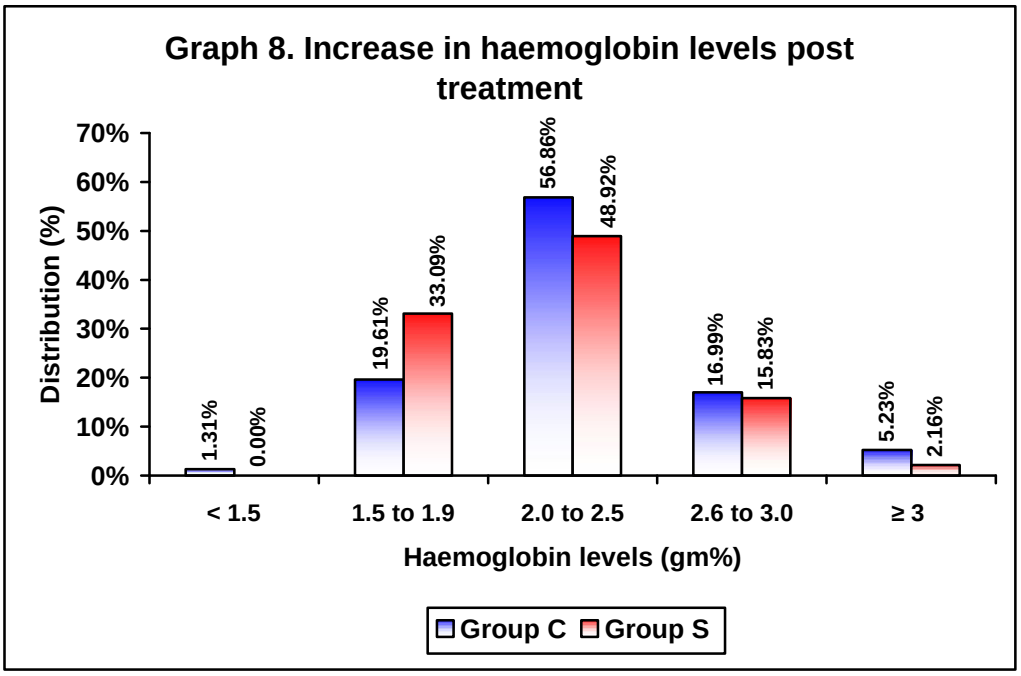
	Group C (n=153)		Group S (n=139)		p value
	Mean	**SD**	**Mean**	**SD**	
Hb (gm%)	10.97	0.79	11.02	0.75	0.617

In the present study post treatment haemoglobin levels were comparable in group C and group S (10.97 ± 0.79 vs 11.02 ± 0.75 gm%; p=0.617).

Table 17. Increase in haemoglobin levels post treatment

Haemoglobin levels (gm%)	Group C (n=153)		Group S (n=139)	
	Number	Percentage	Number	Percentage
< 1.5	2	1.31	0	0.00
1.5 to 1.9	30	19.61	46	33.09
2.0 to 2.5	87	56.86	68	48.92
2.6 to 3.0	26	16.99	22	15.83
≥ 3	8	5.23	3	2.16
Total	**153**	**100.00**	**139**	**100.00**

p = 0.047



In the present study, post treatment mean increase in haemoglobin levels was noted between 2.0 to 2.5 gm% in 56.86% of the women in group C compared to 48.82% in group S and this difference was statistically significant (p=0.047)

Table 18. Mean increase in haemoglobin levels post treatment

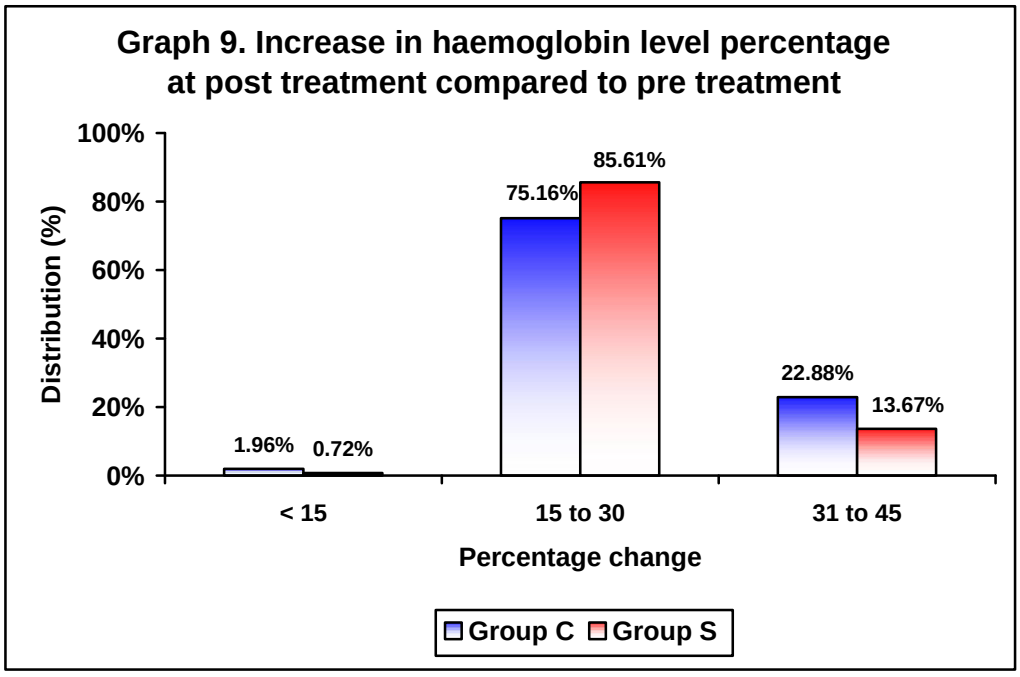
Variable	Group C (n=153)		Group S (n=139)		p value
	Mean	SD	Mean	SD	
Hb (gm%)	2.27	0.39	2.17	0.39	0.023

In the present study the mean increase in haemoglobin levels post treatment were significantly high in group C (2.27 ± 0.39 gm%) compared to group S (2.17 ± 0.39 gm%) (p=0.023).

Table 19. Increase in haemoglobin level percentage at post treatment compared to pre treatment

Percentage change	Group C (n=153)		Group S (n=139)	
	Number	Percentage	Number	Percentage
< 15	3	1.96	1	0.72
15 to 30	115	75.16	119	85.61
31 to 45	35	22.88	19	13.67
Total	**153**	**100.00**	**139**	**100.00**

p = 0.076



In this study 75.16% of the women in group C were found to have increase in haemoglobin percentage between 15 to 30 percent compared to 85.61% in group S. However the difference was statistically not significant (p=0.076)

Table 20. Mean increase in haemoglobin level percentage at post treatment compared to pre treatment

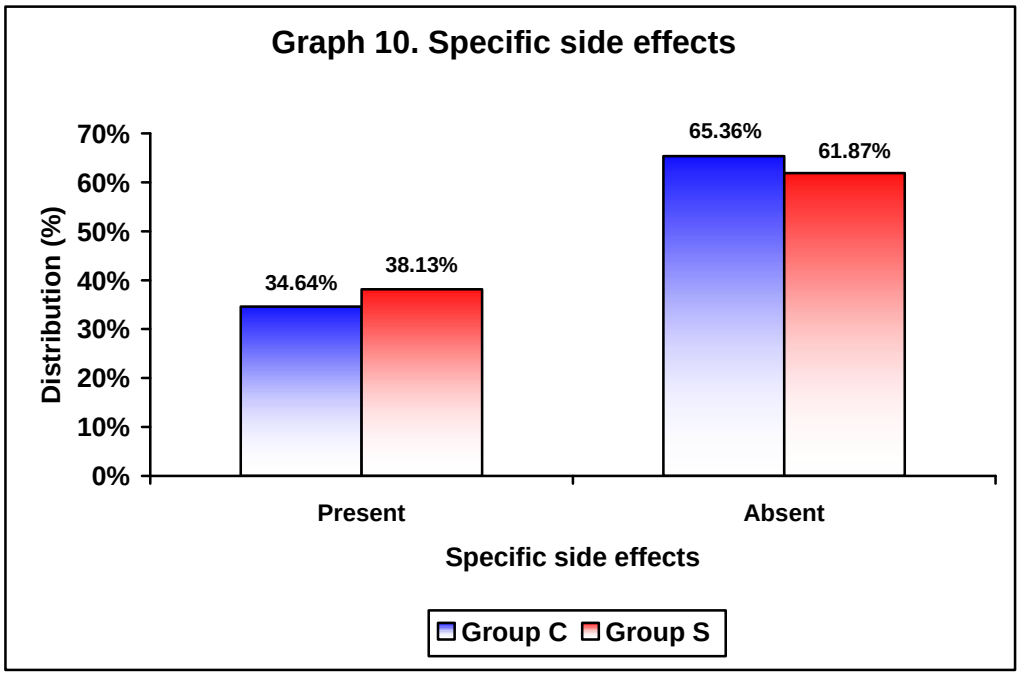
Variable	Group C (n=153)		Group S (n=139)		p value
	Mean	SD	Mean	SD	
Percentage change	26.54	5.98	24.99	6.06	0.029

In this study the mean percentage change in haemoglobin levels post treatment was significantly high in group C (26.54 ± 5.98 percent) compared to group S (24.99 ± 6.06 percent) (p=0.029).

Table 21. Specific side effects

Specific side effects	Group C (n=153)		Group S (n=139)	
	Number	**Percentage**	**Number**	**Percentage**
Present	53	34.64	53	38.13
Absent	100	65.36	86	61.87
Total	**153**	**100.00**	**139**	**100.00**

p = 0.536



In the present study side effects were noted in 36.64% of the women in group C and 38.13% in group S. However, the difference was statistically not significant (p=0.536).

Table 22. Side effects

Specific side effects	Group C (n=153)		Group S (n=139)		p value
	No.	%	No.	%	
Headache	12	7.84	10	7.19	0.834
Dizziness	6	3.92	8	5.76	0.464
Parasthesia	1	0.65	3	2.16	0.269
Hypotension	2	1.31	2	1.44	0.652
Nausea	13	8.50	12	8.63	0.967
Abdominal pain	7	4.58	8	5.76	0.648
Constipation	5	3.27	3	2.16	0.416
Diarrhoea	2	1.31	5	3.60	0.186
Administration site reaction	7	4.58	8	5.76	0.648
Myalgia	15	9.80	7	5.04	0.123
Pyrexia	13	8.50	4	2.88	0.041
Chest pain	5	3.27	3	2.16	0.416
Rigors	4	2.61	3	2.16	0.553

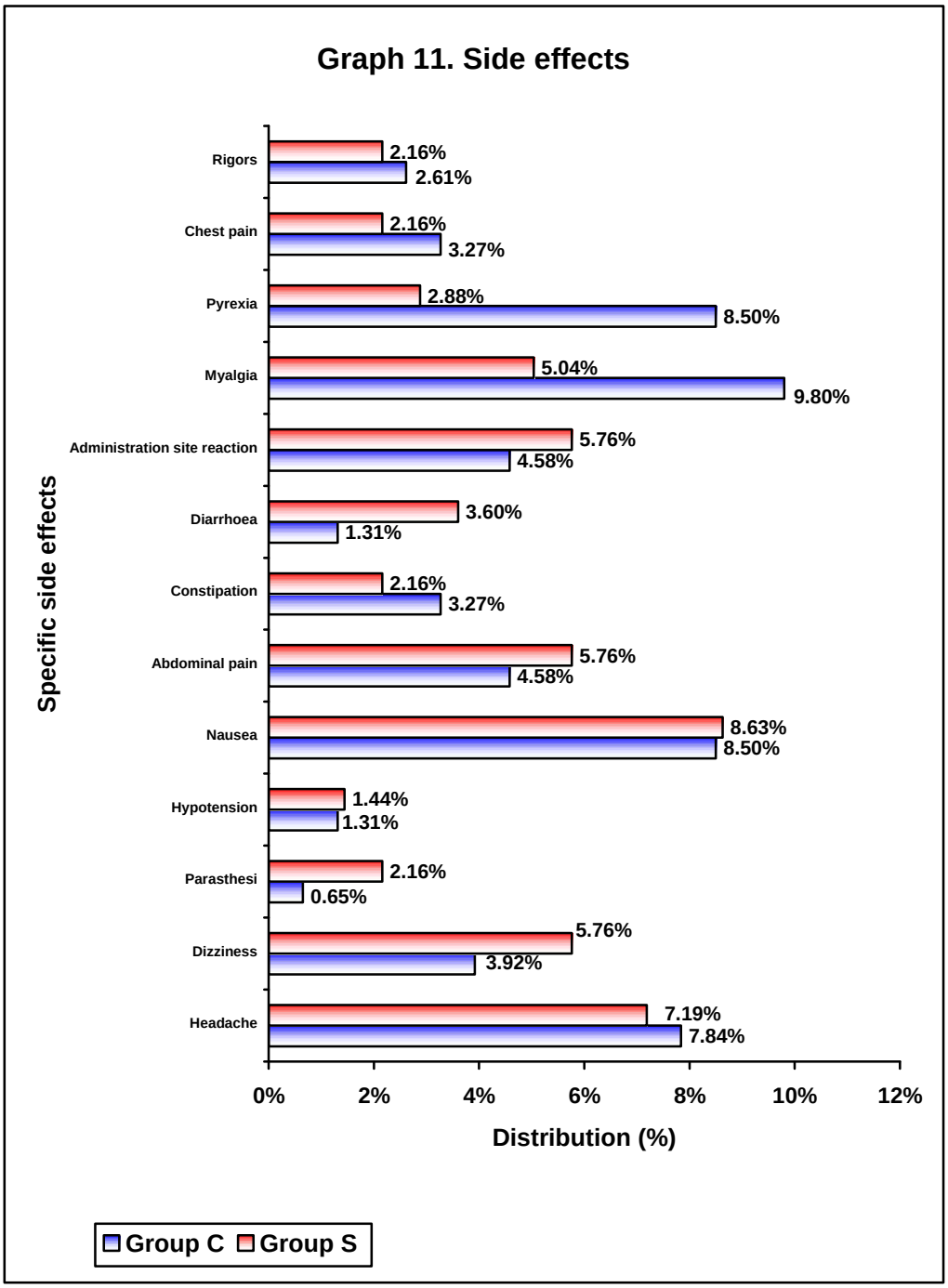


Table 22 and graph 11 shows side effects noted in group C and group S. It was observed that significantly higher number of women had pyrexia in group C (8.5%) compared to group S (2.88%) (p=0.041). Patients had more than one side effects with commonest combination of pyrexia with nausea and headache.

DISCUSSION

Anaemia in pregnancy is associated with adverse consequences both for the mother and the foetus. Studies have shown that the adverse consequences of maternal anaemia may affect not only the neonate and infant but also increase the risk of non communicable diseases when the child grows into an adult and the risk of low birth weight in the next generation.[4]

Earlier, a variety of routine methods such as oral iron therapy, intramuscular iron therapy and blood transfusion were used to treat anaemia during pregnancy. These methods are not without deficiencies and also there are conditions in which these iron therapies are not helpful. There is the problem of inadequate gastrointestinal absorption, intolerance to oral iron, requirement of emergency supplement and severe anaemia with contraindications to blood transfusion. To treat these conditions, a relatively better mode of iron therapy with better efficacy, less side effects, fast action and better compliance is implicated.[77]

Ferric carboxymaltose has been recently introduced for the treatment of anaemia which can be used intravenously in high doses up to 1000 mg with low risk of side effects. At present it is approved in the second and third trimesters of pregnancy but there are very few studies available. This study was aimed to compare i.v. ferric carboxymaltose with i.v. iron sucrose during pregnancy regarding the efficacy, tolerability and safety profile.

This randomized control trial was carried out in the department of Obstetrics and Gynaecology, KLES Dr Prabhakar Kore Hospital and Medical Research Centre,

Belgaum. A total of 305 pregnant women presenting with anaemia from January 2013 to July 2014 were included in the study These women were randomized into two groups comprising of 158 in group C (Received iron carboxymaltose transfusion) and 147 in Group S (Received iron sucrose transfusion). However, the outcome data was available among 153 in group C as five women were lost to follow up and of the 139 in group S and seven women were lost to follow up and one women delivered.

In the present study the commonest age group in group C (39.87%) and S (38.85%) was 21 to 25 years (p=0.312). The mean in group C was 25.33 ± 3.53 years and in group S it was 24.85 ± 4.18 years (p=0.082). Nearly two thirds (62.75%) were housewives in group C compared to 56.83% in group S (p=0.303). With regard to educational status most of the women in group C and S (48.37% and 46.04% respectively) were able to read and write (p=0.059). Higher number of women in group C (44.44%) had class III socio economic status compared to group S (33.81%) but the difference observed was statistically not significant (p=0.253). These findings suggest that the socio-demographic characteristics of the study population were comparable except socio economic class.

With regard to obstetric history, most of the women reported multi parity that is 56.86% in group C and 66.91% in group S but no statistically significant difference was noted (p=0.078). In group C, the gestational age in 83.01% of the women was more than 28 weeks compared to 88.49% in group S (p=0.182). The mean period of gestation in group C was found to be 30.61 ± 4.05 weeks and in group S it was 30.77 ± 3.28 weeks (p=0.706). These findings rule out the possible bias of obstetric history in group C and S.

In the present study based on clinical examination, 73.86% of the women had BMI between 19.8 to 26 Kg/m^2 in group C compared to 75.54% in group S (p=0.747). The mean BMI in group C and S was also comparable (21.92 ± 2.69 vs 21.69 ± 2.56 Kg/m^2; p=0.464). On general examination the mean pulse rate, systolic blood pressure and diastolic blood pressure were comparable in both the groups (p>0.050) showing that the clinical characteristics of the study population in group C and S did not differ.

In this study pretreatment haemoglobin levels in majority of the women from group C (93.46%) and group S (92.81%) were suggestive of moderate anaemia (Haemoglobin levels from 7.0 to 9.9) (p=0.824). The mean pre-treatment haemoglobin levels were also comparable in group C and S that is 8.70 ± 0.84 gm% in group C and 8.82 ± 0.84 gm% in group S (p=0.205). The mean iron requirement in group C was also comparable that is, 809.19 ± 115.77 compared to 783.35 ± 112.59 in group S (p=0.054).

In this study post treatment, more than half of the study population (54.25%) had normal haemoglobin levels (11 gm% or more) in group C and group S (56.12%) (p=0.512). The mean haemoglobin levels in group C were 10.97 ± 0.79 gm% compared to 11.02 ± 0.75 gm% in group S (p=0.617). But, significantly higher number of women in group C had the increase in haemoglobin levels between 2.0 to 2.5 gm% (56.86%) compared to group S (48.82%) (p=0.047). Also the mean increase in haemoglobin levels post treatment were significantly high in group C compared to group S (2.27 ± 0.39 gm% vs 2.17 ± 0.39 gm%; p=0.023). However the percentage of rise in haemoglobin levels was comparable in group C and S that is, 75.16% of the women in group C were found to have increase in haemoglobin levels

between 15 to 30 percent compared to 85.61% of the women in group S (p=0.076). Surprisingly, the mean percentage change in haemoglobin levels post treatment was significantly high in group C compared to group S (26.54 ± 5.98 compared 24.99 ± 6.06 percent; p=0.029). These findings suggest that, treatment of anaemia with intravenous iron carboxymaltose is superior compared to intravenous iron sucrose in the treatment of iron deficiency anaemia among pregnant women.

IV iron sucrose (IS) has been used for many years to treat iron deficiency in pregnant women after the first trimester. However its use is limited by a low maximum dose due to side effects at higher doses. IV ferric carboxymaltose (FCM) can be administered at a higher doses and has a good side-effect profile. Ferric carboxymaltose is approved for use in pregnancy in the second and third trimesters. However up to now no published data from clinical studies investigating the use of ferric carboxymaltose in pregnancy are available.[68]

The rapid delivery option of a large single dose of ferric carboxymaltose offers a promising treatment modality for pregnant women who need correction of iron deficiency and anaemia over other IV iron formulations that have low dosage limits, such as iron sucrose (200 mg).

Christoph et al.[68] undertook a retrospective analysis of 206 pregnant women who were treated either with FCM (n=103) or IS (n=103) to assess maternal tolerability and safety and to exclude safety concerns for the foetus. The incidence of drug-related adverse events was low and mostly mild in both groups, patients treated with FCM had fewer side effects (FCM, 7.8%; IS, 10.7%, NS). The mean rise of haemoglobin was 15.4 g/L for FCM and 11.7 g/L for IS. This study

nevertheless showed that the tolerance of FCM in pregnancy is good and that side effects are rare, even when administered in a much higher dose than IS and it also offers the advantage of requiring less administrations thereby increasing patient comfort. The authors concluded that FCM would seem to be the drug of choice if IV iron treatment is necessary in the second or third trimester of pregnancy. The findings of the present study were in agreement with the results of Christoph et al.[61] except the mean haemoglobin levels which were 11.36 ± 0.92 in the present study compared to 15.4 g/L.

In a prospective observational study done by Bernd Froessler et al.[62] in Australia 65 anaemic pregnant women received ferric carboxymaltose up to 15 mg/kg between 24 and 40 weeks of pregnancy. Intravenous ferric carboxymaltose infusion significantly increased Hb values ($p<0.01$) above baseline levels in all women. Increased Hb values were observed at 3 and 6 weeks post infusion and up to 8 weeks post-infusion. Fetal heart rate monitoring did not indicate a drug related negative impact on the foetus. No serious adverse effects were found and minor side effects occurred in 13 (20%) patients. Even though the rise in haemoglobin in our study was comparable to this study, the incidence of adverse side effects in our study was more.

Myers B et al.[78] conducted a retrospective analysis of pregnant women treated with ferric carboxymaltose and iron dextran. Of the 92 women, 44 received i.v FCM and 48 received i.v Iron Dextran . At two weeks, the mean Hb rise in the FCM group was 1.73 g/dL and 1.34 g/dL in the Iron Dextran group. At four weeks, the total rise in Hb was 2.57 g/dL FCM, 2.34 g/dL Iron Dextran. At six weeks the

rise was 3.01 g/dL and 3.2 g/dL respectively. The rise in Hb at the end of four weeks was comparable to our study.

Another randomised open trial compared IV ferric carboxymaltose with IV iron sucrose for treating iron deficiency anaemia secondary to inflammatory bowel disease (ulcerative colitis and Crohn's disease) in 475 patients.[79] Patients had initial Hb levels below 120 g/L in women or 130 g/L in men. The primary outcome of increase in Hb by at least 20 g/L was achieved by 66% with ferric carboxymaltose and 54% with iron sucrose. Achievement of a normal Hb occurred in 73% with ferric carboxymaltose and 62% for iron sucrose; normal TSAT (20-50%) was achieved in 53% and 36%, and normal ferritin (≥100 μg/L) by 43% and 27% respectively. The time course for these changes was similar to that seen in the oral iron comparisons. This study also compared cost effectiveness of the two regimens. Although ferric carboxymaltose has a higher cost per treatment than iron sucrose (US$ 311 vs 154), the greater number of infusions with iron sucrose resulted in a higher overall treatment cost (US$ 653 for ferric carboxymaltose and US$ 891 for iron sucrose). Treatment with iron sucrose thus costs US$ 238 more than ferric carboxymaltose, but with a 12% lower chance of hitting the target increase in Hb.

In the present study 36.64% of the pregnant women had side effects in group C compared to 38.13% in group S but the difference was statistically not significant (p=0.536) suggesting that the safety of intravenous iron carboxymaltose is comparable with intravenous ferric sucrose. The common side effects noted with iron carboxymaltose were myalgia (9.8%), pyrexia (8.5%), nausea (8.5%), headache (7.84%) and abdominal pain (4.58%) which were comparable with women who

underwent treatment with intravenous ferric sucrose except pyrexia which was significant low in group S (2.88%; p=0.041) compared to group S.

The tolerance and efficacy of ferric carboxymaltose has been demonstrated previously in several studies for different groups of patients with iron-deficiency anaemia[70,80-83] with similar results. Bailie GR[81] showed in a review paper, including nine randomized studies with more than 3000 patients, that ferric carboxymaltose had a good tolerability and efficiency profile. The use of ferric carboxymaltose for treatment of postpartum anaemia has been extensively investigated.[70,75,80,84] No safety concerns have been identified in breastfed infants of mothers receiving ferric carboxymaltose.[70]

In the three cohort studies[85-87] 345 patients were treated with IV ferric carboxymaltose. Of these 75 (21%) withdrew for any reason, and 14 (4%) because of adverse events. At least one adverse event was experienced by 197 (56%), serious adverse events by 35 (10%), and hypotension by 10 (3%).

Overall, the data from this study is consistent with existing data that intravenous iron carboxymaltose administration in pregnancy is likely to be safe and effective. However the limitation of the study was that due to the limited financial assistance blood indices like serum ferritin, transferin saturation and other indices for iron deficiency anaemia was not feasible in our study. Ideally measuring serum ferritin levels would have been a better marker for noting the efficacy of the treatment. Furthermore the follow up of patients was done only at the end of four weeks. Serial follow ups at the end of two, four, six and eight weeks would have been better in observing the trend in rise of haemoglobin values. Since the duration

of our study was only one and half year the follow up of the neonates and infants was not included in the study.

The cost of the Ferric Carboxymaltose drug is relatively high when compared to other available parentral iron preparations. This high cost of the drug is very well compensated when the number of visits and number of days of hospital admission is taken in to account. However studies for observing the cost effectiveness of the treatment needs to taken up. Further studies including large number of women in a randomized controlled trial along with the long term follow up of the neonates would extend the effectiveness, safety and efficacy of intravenous ferric carboxymaltose in the treatment of iron deficiency anaemia in pregnancy.

CONCLUSION

Based on the results of this study it may be concluded that, the intravenous iron carboxymaltose is more effective in the treatment of iron deficiency anaemia among pregnant women compared to intravenous iron sucrose. Further it is well tolerated in pregnant women as side effects are comparable to that of iron sucrose except pyrexia.

SUMMARY

Ferric carboxymaltose has been recently introduced for the treatment of anaemia. The present study was planned to compare the efficacy, tolerability and safety of intravenous ferric carboxymaltose with intravenous iron sucrose in the treatment of iron deficiency anaemia among pregnant women.

The present one year randomized control trial was done from January 2013 to July 2014 in the department of Obstetrics and Gynaecology, KLES Dr Prabhakar Kore Hospital and Medical Research Centre, Belgaum. A total of 305 pregnant women were randomized into two groups comprising of 158 in group C (Received iron carboxymaltose transfusion) and 147 in Group S (Received iron sucrose transfusion). The outcome data was available among 153 in group C and 139 in group S.

In the present study the commonest age group was 26 to 30 years in group C comprised of 40.52% compared to 21 to 25 years in group S with 38.85% of the women (p=0.312) and mean age of the study population in group C and S was comparable (25.33 ± 3.53 vs 24.85 ± 4.18 years; p=0.082) The other socio demographic characteristics of the study population including occupation (p=0.303), educational status (p=0.059), socio economic status (p=0.253) were comparable. Further the obstetric history including parity (p=0.078), gestational age at enrolment (p=0.182), mean period of gestation (p=0.706), body mass index (p=0.747), mean body mass index (p=0.464) were also comparable. On examination, vitals including pulse rate and blood pressure did not differ in both the groups (p>0.050). The pretreatment heamoglobin levels were between 7.0 to 9.9 in group C among 93.46%

women compared to 92.81% in group S (p=0.824). The post treatment haemoglobin levels in 54.9% of the women were found to be 11 or more in group C compared to 56.12% in group S (p=0.614) and mean post treatment haemoglobin levels were comparable in group C and group S (11.59±7.72 vs 11.02±0.75 gm%; p=0.358). However, significantly higher number of women in group C had increase in haemoglobin levels between 2.0 to 2.5 gm% (56.86%) compared to in group S (48.82%) (p=0.047). The mean increase in haemoglobin levels post treatment was significantly high in group C (2.27 ± 0.39 gm%) compared to group S (2.17 ± 0.39 gm%) (p=0.023). In group C, 75.16% of the women were found to have increase in haemoglobin percentage between 15 to 30 percent compared to 85.61% in group S (p=0.076) and the mean percentage change in haemoglobin levels post treatment was significantly high in group C (26.54 ± 5.98 percent) compared to group S (24.99 ± 6.06 percent) (p=0.029). The side effects were noted in 36.64% of the women in group C and 38.13% in group S (p=0.536) and significantly higher number of women had pyrexia in group C (8.5%) compared to group S (2.88%) (p=0.041).

Intravenous iron carboxymaltose is more effective in the treatment of iron deficiency anaemia among pregnant women compared to intravenous iron sucrose. Further it is well tolerated in pregnant women as side effects are comparable to that of iron sucrose except pyrexia.

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ANNEXURE I – CONSENT FORM

I.D.NO.

Comparison of efficacy and safety of intravenous ferric carboxymaltose vs iron sucrose in the treatment of antepartum iron deficiency anaemia – A randomized controlled trial KLE Dr.Prabhakar Kore Hospital & MRC

The study is conducted by Dr. **** *****, post graduate student in M.S Obstetrics and Gynaecology under guidance of Dr. *** ******, Professor of Obstetrics and Gynaecology, J N Medical College, Belgaum.

Respected Sir/Madam, we invite you to participate in our study as, you are eligible for the same. During the study you will be asked some questions in detail regarding your present complaints and you will be randomised into control group and trial group. All the patients in the control group will be administered intravenous iron sucrose and in the trial group intravenous iron carboxymaltose will be administered to correct iron deficiency anaemia.

Purpose of the study:

The purpose of this study is to evaluate the mean rise in haemoglobin at the end of 6 weeks after administration of intravenous iron carboxymaltose compared with intravenous ferric sucrose for the treatment of iron deficiency anaemia in pregnant women. You are being asked to participate in this research because your baseline haemoglobin is within the range of 7 to 10 gm/dl and diagnosed to have iron deficiency anaemia. All patients admitted in the antenatal ward, who are

diagnosed to have iron deficiency anaemia, will be requested to participate in this study during the period of one year.

Procedure and treatment:

Should you choose to participate, you will be asked to give a detailed history of your disease, undergo a physical examination, and will be randomised into control and trial groups. The haemoglobin deficit will be corrected by intravenous iron therapy either by iron carboxymaltose or iron sucrose depending on the group assigned to you.

Risks and benefits:

You may undergo some amount of discomfort during the process of intravenous iron infusion, which may include local pain, swelling, mild local reactions at the injection site and mild systemic reactions. However all necessary steps and precautions will be taken to ensure your safety. The result of you taking part in this research would help health care providers towards a better understanding of efficacy and safety of intravenous ferric carboxymaltose.

Alternatives:

If you decide not to participate in this study, you will still be receiving the usual standard care for your disease.

Privacy and confidentiality:

Your privacy will be respected and all information collected about you during the course of this study will be kept confidential. Your identity will remain undisclosed.

Relations with the Institutional policy:

The J N Medical College will provide, within the limitations of the laws of the State of Karnataka, facilities and medical attention to patients who suffer injuries as a result of participating in this project. In the event if you suffer any physical injury as the result of your participation in this study, you may contact Dr. **** ****** Telephone No. ***** ******* or Dr. ***** *****, Telephone No. **** *****. In the event of an emergency, you should contact KLE'S Dr. Prabhakar Kore Hospital and MRC on Telephone No. ***** *******.

Financial incentives:

You shall not be receiving any payment or any financial incentives for participating in this study.

Authorization to publish results:

The results of this study may be published for scientific purpose or presented to a scientific group. Your identity, however, will be maintained confidential at all times.

Voluntary participation:

Your participation in this study is voluntary. Your decision whether or not to participate will neither affect the care of your current disease, nor your future relations with the doctor or the hospital. In case you need further information regarding your rights as a study participant, you may please contact Dr. **** ******, principal and chairman of the ethical committee, J N Medical College, Belgaum on telephone No. ***** ******

Statement of Consent:

I.D.NO: | | | |

I Mr/Ms/Mrs _____Volunteer and consent to participate in this study. I have read the consent document or it has been read to me in my vernacular language. I accept to participate in the study. All the information regarding this study is provided to me and I have understood the same. I have been given the opportunity to ask questions and obtain appropriate answers.

Participant's name:

Signature or left thumb print of participant:

Witness name:

Signature of witness:

Signature of the investigator:

Date:

If the participants are Minors (under 18), the parents sign the form, rather than the participants.

ANNEXURE II – PROFORMA

Title: *"Comparison of efficacy and safety of intravenous ferric carboxymaltose vs iron sucrose in the treatment of antepartum iron deficiency anaemia – A randomized controlled trial"*

Screening ID. No				
Id.No:				
OPD NO :				
IPD NO :		Unit:		
DATE :				
COMPUTERISED RANDOMIZATION NO:				
GROUP ASSIGNED :	IRON CARBOXYMALTOSE		IRON SUCROSE	

PATIENTS NAME :	F :	M :	S :
AGE :			
ADDRESS :			

1 SCREENING

1.Is the pregnant woman of ≥ 12 weeks gestation	YES		NO	
2.Is it a singleton pregnancy?	YES		NO	
3.Is the baseline haemoglobin > 7 gm/dl and < 10 gm/dl ?	YES		NO	
4.Is there any maternal medical complications present?	YES		NO	

5.If ans is yes to Q.4 then specify?				
6.Is the woman willing to give consent?	YES		NO	
7.Final result:	Eligible participating			
	Eligible refusal			
	Ineligible			

2 DEMOGRAPHIC AND OBSTETRIC DATA

8.OCCUPATION:	HOUSE WIFE	
	WORKING	
	LABOURER	
	PROFESSIONAL	
9. EDUCATION :	ILLITERATE	
	CAN READ	
	CAN WRITE	
	PRIMARY	
	SECONDARY	
	GRADUATE	
	POST GRADUATE	
10. SOCIOECONOMUC STATUS:	CLASS 1	
	CLASS 2	
	CLASS 3	
	CLASS 4	

11.OBSTETRIC SCORE :	GRAVIDA	
	PARA	
	LIVING	
	ABORTION	
12. LMP :		
13. EDD(BY DATES) :		
14. EDD (BY SCAN) :		
15. ESTIMATED PERIOD OF GESTATION :		

3 <u>EXAMINATION</u>

16. HEIGHT (in cms) :		
17. WEIGHT (in kgs) :		
18. BMI (kg/ m^2) :		
19. PULSE RATE :		
20. BLOOD PRESSURE :	SYSTOLIC	
	DIASTOLIC	

SYSTEMIC EXAMINATION				
21. Is cardiovascular system normal?	YES		NO	
22.Is respiratory system normal?	YES		NO	
23.After examination is she eligible?	YES		NO	
24.Is she randomized?	YES		NO	
25.Pre- treatment Hb%(in gms)				

4 PARENTRAL IRON TRANSFUSION

26.Required dose of iron		
27.Dosage of iron transfused		
28 Number of infusions		
29. Any adverse side effect noted	A. Infusion site burning	
	B. Urticaria	
	C. Tachycardia	
	D. Hyopotension	
	E. Hypertension	
30. Specific adverse effects	A. Severe allergic reaction	
	B. Constipation	
	C. Diarrhoea	
	D. Abdominal pain	
	E. Nausea/ vomiting	
31. Death		

5 POST TREATMENT DETAILS

32. Post treatment Hb % (in gms)		
33. Rise in haemoglobin at the end of treatment		
34. Was there any need for blood transfusion		
35. Withdrawal from the study	A. All causes	
	B. Due to adverse effects	
	C. Due to lack of efficacy	

6. NOTES :

_____

_____

_____

_____

_____

ANNEXURE III – KEY TO MASTER CHART

BP	-	Blood pressure
C	-	Iron carboxymaltose
Cms	-	Centimeters
gm	-	Gram
GR	-	Graduate
HW	-	House wife
IL	-	Illiterate
Kg/m^2	-	Kilogram per square meter
Kgs	-	Kilograms
mg	-	Milligram
mm Hg	-	Millimeters of mercury
N	-	No
n	-	Normal
PR	-	Professional
RW	-	Read and write
S	-	Intravenous iron sucrose
SC	-	Secondary
W	-	Working
Y	-	Yes

ANNEXURE III - MASTER CHART

Serial Number	In Patient Number	Randomization Number	Group	Age (Years)	Demographic data			Obstetric score				Period of gestation (weeks)	Examination						Pre treatment haemoglobin (gm%)	Parenteral iron transfusion			Adverse effects																											Post treatment			Withdrawal from study
																	BP																																		
					Occupation	Education	Socio economic status	Gravida	Para	Living	Abortion		Height (Cms)	Weight (Kgs)	BMI (Kg/m^2)	Pulse rate (per minute)	Systolic (mm Hg)	Diastolic (mm Hg)	Systemic examination		Required dose (mg)	Doses (mg)	Number of Infusions	Hypersensitivity reaction	Headache	Dizziness	Parasthesia	Hypotension	Hypertension	Flushing	Dyspnea	Nausea	Abdominal pain	Constipation	Diarrhoea	Administrative site reactions	Myalgia	Pyrexia	Chest pain	Rigors	Death	Haemoglobin (gm%)	Rise in haemoglobin (gm%)	Blood transfusion	
1	526425	1	C	28	HW	PR	2	1	-	-	-	30	158	50	20.08	80	110	70	n	8.1	800	800	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.2	3.1	N	N
2	525070	2	S	19	HW	PR	2	1	-	-	-	35	152	48	20.77	80	110	70	n	8.9	700	700	4	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.4	2.5	N	N
3	524976	3	S	22	W	RW	3	1	-	-	-	30	152	54	23.47	80	126	80	n	8.9	700	700	4	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	Y	N	11.1	2.3	N	N
4	524655	4	S	25	W	IL	2	2	-	-	1	28	152	59	24.68	76	110	70	n	7.6	981	1000	5	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.4	2.8	N	N
5	527069	5	C	20	HW	PR	3	1	-	-	-	26	153	56	23.93	80	116	80	n	8.5	836	1000	1	N	N	N	N	N	N	N	N	N	N	N	N	N	Y	Y	N	N	10.8	2.2	N	N
6	527141	6	C	21	HW	PR	1	1	-	-	-	33	164	57	21.20	86	112	78	n	9.5	705	700	1	N	N	Y	N	N	N	N	N	Y	N	N	N	Y	N	Y	N	N	12.3	2.8	N	N
7	523021	7	S	20	HW	PR	2	1	-	-	-	22	158	50	20.08	76	110	82	n	8	980	1000	5	N	N	N	N	N	N	N	N	Y	N	N	N	N	N	N	N	N	10.2	2.2	N	N
8	525981	8	S	24	W	SC	1	5	1	1	3	30	148	40	18.26	80	118	70	n	9.9	588	600	3	N	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	12.4	2.5	N	N
9	526753	9	C	24	HW	PR	2	2	1	1	-	35	152	52	22.51	76	108	70	n	9.5	687	700	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.8	2.2	N	N
10	525658	10	S	21	HW	PR	3	2	1	1	-	35	157	50	20.32	80	110	80	n	7.4	932	1000	5	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	9.6	2.2	N	N
11	527523	11	C	24	HW	PR	3	2	1	1	-	32	156	67	27.57	82	116	80	n	8.9	1000	1000	1	N	Y	Y	N	N	N	N	N	Y	N	N	N	N	Y	N	N	11.6	2.8	N	N
12	526776	12	S	20	W	PR	2	1	-	-	-	31	147	47	21.75	78	110	70	n	8.6	776	800	4	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.2	2.6	N	N
13	527724	13	C	19	HW	PR	1	1	-	-	-	30	157	50	20.30	76	128	80	n	7.5	1076	1000	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	9.5	2	N	N
14	521658	14	S	21	W	PR	2	2	1	1	-	35	157	50	20.32	80	112	80	n	7.4	932	1000	5	N	N	N	N	N	N	N	N	N	N	N	Y	N	N	N	N	N	10.3	2.9	N	N
15	471164	15	C	29	HW	PR	2	5	4	3	-	34	160	58	22.60	80	110	70	n	8.6	800	800	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.3	2.7	N	N
16	526832	16	S	20	HW	PR	2	1	-	-	-	32	158	44	17.67	72	106	80	n	7.5	869	900	5	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.2	2.7	N	N
17	471722	17	C	20	W	PR	3	1	-	-	-	33	150	52	23.10	80	108	80	n	7.7	911	1000	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	9.8	3.1	N	N
18	472559	18	C	27	HW	PR	2	1	-	-	-	34	148	42	19.17	72	106	70	n	7.8	900	1000	1	N	Y	Y	N	N	N	N	N	N	N	N	N	N	N	Y	N	N	10.6	2.8	N	N
19	525981	19	S	24	HW	PR	3	5	1	1	3	30	148	38	17.35	84	118	72	n	9	788	800	4	N	N	N	N	N	N	N	N	Y	N	N	N	N	N	N	N	N	-	-	-	Y
20	472406	20	C	23	W	RW	1	2	-	-	1	28	154	52	21.94	80	116	72	n	8.6	799	800	1	N	N	N	N	N	N	N	N	N	N	N	N	Y	N	N	N	Y	N	11.5	2.9	N	N
21	472950	21	C	24	W	RW	1	3	2	2	-	26	158	56	22.48	80	116	80	n	9.1	755	800	1	N	N	N	N	N	N	N	N	Y	N	N	N	N	N	N	N	N	12	2.9	N	N
22	473303	22	S	20	W	RW	1	2	1	1	-	35	161	58	22.39	78	118	68	n	7.8	949	1000	5	N	Y	N	N	N	N	N	N	N	Y	N	N	N	N	N	N	N	10.5	2.7	N	N
23	474183	23	S	21	W	RW	2	2	-	-	1	32	166	60	23.43	72	110	80	n	9.2	759	800	4	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.1	1.9	N	N
24	473813	24	S	24	HW	PR	3	1	-	-	-	31	146	38	17.84	72	108	70	n	7.2	846	800	4	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	9.3	2.1	N	N
25	474516	25	S	24	W	PR	3	2	1	0	-	30	158	46	18.47	80	108	70	n	9.6	654	600	3	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	Y	N	12.5	2.9	N	N
26	533405	26	C	30	W	PR	2	1	-	-	-	32	166	56	20.36	78	118	72	n	8.2	876	800	1	N	N	N	N	N	N	N	N	N	N	Y	N	Y	Y	N	N	N	N	11.5	3.2	N	N
27	533648	27	C	30	HW	PR	1	2	1	1	-	28	170	69	21.56	88	124	80	n	8.9	847	800	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.1	2.3	N	N
28	533962	28	C	26	W	RW	3	3	2	2	-	26	156	58	23.86	80	126	88	n	8.2	889	900	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	Y	N	N	10.1	2.1	N	N
29	534030	29	C	23	HW	PR	2	1	-	-	-	32	160	58	22.65	72	130	80	n	7.6	937	1000	5	N	N	N	N	N	N	N	N	N	N	N	N	N	Y	Y	N	N	10.5	2.9	N	N
30	536685	30	S	30	HW	PR	1	3	2	1	-	28	158	56	22.48	80	110	70	n	7.2	1100	1100	2	N	N	N	N	N	N	N	N	N	Y	N	N	N	Y	N	N	N	10.4	3.2	N	N
31	534059	31	C	27	HW	PR	3	1	-	-	-	31	164	57	22.90	84	124	76	n	8.2	883	1000	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.1	2.9	N	N
32	536803	32	C	20	HW	RW	4	1	-	-	-	33	168	68	24.20	72	110	76	n	8.6	891	900	1	N	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.7	3.1	N	N

ANNEXURE III - MASTER CHART

Serial Number	In Patient Number	Randomization Number	Group	Age (Years)	Demographic data			Obstetric score				Period of gestation (weeks)	Examination							Pre treatment haemoglobin (gm%)	Parenteral iron transfusion			Adverse effects																												Post treatment			Withdrawal from study
																	BP																																				
					Occupation	Education	Socio economic status	Gravida	Para	Living	Abortion		Height (Cms)	Weight (Kgs)	BMI (Kg/m^2)	Pulse rate (per minute)	Systolic (mm Hg)	Diastolic (mm Hg)	Systemic examination		Required dose (mg)	Doses (mg)	Number of Infusions	Hypersensitivity reaction	Headache	Dizziness	Parasthesia	Hypotension	Hypertension	Flushing	Dyspnea	Nausea	Abdominal pain	Constipation	Diarrhoea	Administrative site reactions	Myalgia	Pyrexia	Chest pain	Rigors	Death	Haemoglobin (gm%)	Rise in haemoglobin (gm%)	Blood transfusion	
33	534480	33	S	26	HW	PR	2	2	-	-	1	33	155	56	24.20	84	124	80	n	9.2	741	800	4	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	12	2.8	N	N
34	537359	34	S	22	W	RW	3	3	1	1	1	34	160	48	18.75	70	108	80	n	9.8	638	600	3	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	12.4	2.6	N	N
35	537590	35	C	31	W	PR	1	1	-	-	-	32	158	70	28.11	80	126	84	n	9.2	802	800	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.4	2.2	N	N
36	534445	36	S	24	W	PR	2	1	-	-	-	30	158	60	24.20	80	128	76	n	9	788	800	4	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.5	1.5	N	N
37	533820	37	S	19	HW	PR	3	1	-	-	-	32	156	55	22.90	82	120	76	n	8.5	830	800	4	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.3	2.7	N	N
38	528524	38	S	30	HW	PR	3	2	1	1	-	32	158	62	24.80	80	108	68	n	8.6	857	800	4	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.8	2.2	N	N
39	528564	39	S	32	W	RW	3	3	2	1	-	28	154	45	18.98	72	118	76	n	7.2	910	1000	5	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	9.6	2.4	N	N
40	528726	40	S	34	W	RW	3	1	-	-	-	33	160	43	16.79	80	110	80	n	8.6	776	800	4	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.8	2.2	N	N
41	528808	41	S	30	W	RW	3	3	2	2	-	34	148	42	19.17	86	110	72	n	8.5	752	800	4	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.3	2.7	N	N
42	528839	42	C	20	W	PR	2	2	1	1	-	34	154	48	20.20	76	108	72	n	8.9	741	800	1	N	N	Y	N	N	N	N	N	N	Y	Y	N	N	N	N	N	N	N	12	3.1	N	N
43	528921	43	S	20	W	RW	3	2	1	1	-	32	150	52	23.11	82	110	70	n	7.8	900	900	5	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.6	2.8	N	N
44	529134	44	S	19	W	RW	1	1	-	-	-	30	156	54	22.20	82	116	82	n	8.9	772	800	4	N	N	N	N	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	12	3.1	N	N
45	529141	45	C	30	W	RW	3	2	1	1	-	32	160	55	21.48	72	110	76	n	9.6	684	700	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	12.3	2.7	N	N
46	529273	46	S	28	W	RW	3	3	2	1	-	34	148	54	24.65	80	118	82	n	9.2	733	700	4	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-	-	-	Y
47	529387	47	S	26	W	PR	2	1	-	-	-	32	156	46	18.90	72	100	68	n	7.8	853	800	4	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.6	2.8	N	N
48	529392	48	C	27	HW	PR	2	1	-	-	-	33	164	56	23.20	82	130	80	n	8.8	795	800	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11	2.2	N	N
49	529398	49	C	24	HW	RW	3	1	-	-	-	28	150	54	24.00	80	112	80	n	9.4	707	700	1	N	N	N	N	Y	N	N	N	N	N	N	Y	N	N	N	N	N	N	11.6	2.2	N	N
50	529402	50	C	24	HW	RW	3	4	3	2	1	34	156	52	19.20	74	120	76	n	8	874	800	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.1	2.1	N	N
51	529404	51	C	28	HW	PR	2	1	-	-	-	32	160	60	23.43	72	110	70	n	7.2	1047	1000	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10	2.8	N	N
52	529514	52	S	22	W	PR	3	2	1	1	0	33	162	54	20.61	82	118	80	n	8.8	785	800	4	N	N	N	N	N	N	N	N	Y	N	N	N	N	N	N	N	N	N	11.8	3	N	N
53	529495	53	C	29	W	PR	1	1	-	-	-	33	152	55	23.50	72	124	76	n	8.5	830	800	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.2	2.7	N	N
54	529564	54	C	26	W	PR	2	2	1	1	-	32	164	58	23.29	88	130	84	n	8.8	806	800	1	N	Y	N	N	N	N	N	N	Y	N	N	N	N	N	N	N	N	N	11.7	2.9	N	N
55	529578	55	C	26	HW	PR	2	1	-	-	-	32	154	60	24.20	72	112	68	n	7.5	1000	1000	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	9.6	2.1	N	N
56	529585	56	S	25	HW	RW	3	2	1	1	-	34	158	42	16.86	80	110	76	n	7.2	883	800	4	N	N	N	N	N	N	N	N	N	N	Y	N	N	N	N	N	N	N	10.4	3.2	N	N
57	529587	57	C	29	W	RW	3	3	2	2	-	35	162	58	22.13	80	120	80	n	9.2	750	700	1	N	N	N	N	N	N	N	N	N	Y	N	N	N	N	N	N	N	N	11.3	2.1	N	N
58	539955	58	S	25	W	RW	2	3	2	1	-	34	152	58	25.10	80	120	80	n	7.6	973	1000	5	N	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.5	2.9	N	N
59	540955	59	S	20	W	PR	2	1	-	-	-	32	160	53	20.70	76	110	78	n	8.2	856	800	4	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.1	2.9	N	N
60	541190	60	S	26	HW	PR	3	2	1	1	-	33	160	42	15.62	80	126	80	n	8.4	762	800	4	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11	2.6	N	N
61	542030	61	S	28	HW	RW	1	1	-	-	-	35	158	54	21.68	86	120	80	n	9.1	746	800	4	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.8	2.7	N	N
62	539093	62	C	22	HW	PR	1	1	-	-	-	34	164	48	17.90	86	110	80	n	7.6	891	800	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	9.9	2.3	N	N
63	539286	63	S	22	HW	RW	3	1	0	0	-	33	158	40	16.06	92	110	76	n	8.8	742	800	4	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.8	2	N	N
64	539618	64	C	25	HW	RW	3	3	2	2	-	35	162	54	20.61	82	100	72	n	8.8	785	800	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.5	1.7	N	N

ANNEXURE III - MASTER CHART

Serial Number	In Patient Number	Randomization Number	Group	Age (Years)	Demographic data			Obstetric score				Period of gestation (weeks)	Examination						Pre treatment haemoglobin (gm%)	Parenteral iron transfusion			Adverse effects																											Post treatment			Withdrawal from study
																	BP																																		
					Occupation	Education	Socio economic status	Gravida	Para	Living	Abortion		Height (Cms)	Weight (Kgs)	BMI (Kg/m^2)	Pulse rate (per minute)	Systolic (mm Hg)	Diastolic (mm Hg)	Systemic examination		Required dose (mg)	Doses (mg)	Number of Infusions	Hypersensitivity reaction	Headache	Dizziness	Parasthesia	Hypotension	Hypertension	Flushing	Dyspnea	Nausea	Abdominal pain	Constipation	Diarrhoea	Administrative site reactions	Myalgia	Pyrexia	Chest pain	Rigors	Death	Haemoglobin (gm%)	Rise in haemoglobin (gm%)	Blood transfusion	
65	538644	65	C	19	HW	PR	2	1	0	0	-	32	152	48	20.70	90	108	70	n	9.2	707	700	1	N	N	N	N	N	N	N	N	N	N	N	Y	N	N	N	N	N	11.1	1.8	N	N
66	539884	66	S	22	HW	RW	3	3	2	0	-	29	148	51	23.28	88	128	78	n	8.1	854	800	4	N	N	N	N	N	N	N	N	N	N	N	N	N	Y	N	N	N	10.4	2.3	N	N
67	539959	67	S	30	W	PR	2	3	2	2	-	33	162	54	20.60	88	128	84	n	8	888	800	4	N	N	N	N	N	N	N	N	N	N	N	N	N	N	Y	N	N	9.9	1.9	N	N
68	536380	68	C	24	W	RW	3	1	0	0	-	28	164	52	19.40	84	118	76	n	7.6	924	1000	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	Y	N	N	9.7	2.1	N	N
69	541189	69	C	23	HW	RW	3	1	-	-	-	32	166	56	20.30	78	108	70	n	9.2	876	800	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-	-	-	Y
70	541230	70	C	22	HW	RW	3	2	-	-	1	32	156	48	19.75	76	108	80	n	8.6	776	800	1	N	N	N	N	N	N	N	N	N	N	N	N	N	Y	Y	N	N	N	10.5	1.9	N	N
71	543648	71	C	19	W	RW	3	1	-	-	-	22	156	43	21.70	88	106	70	n	7.2	892	1000	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	9.5	2.3	N	N
72	543276	72	S	28	W	RW	4	2	-	-	1	32	148	47	21.46	80	116	80	n	7.8	860	800	4	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	9.9	2.1	N	N
73	594992	73	C	28	HW	PR	2	3	2	2	-	34	150	52	23.10	80	112	70	n	11	580	600	1	N	N	N	N	N	N	N	N	N	N	N	N	Y	N	N	N	N	N	12.5	1.5	N	N
74	545951	74	C	24	HW	RW	3	2	1	1	-	35	146	56	26.29	80	118	70	n	8.6	822	800	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.5	1.9	N	N
75	546369	75	S	21	HW	RW	3	1	-	-	-	21	149	45	20.27	84	112	80	n	9.4	672	600	3	N	N	N	N	N	N	N	N	N	Y	N	N	N	N	N	Y	N	11.5	2.1	N	N
76	545463	76	C	23	HW	PR	1	2	1	1	-	34	139	47	24.35	82	116	80	n	8.7	759	800	1	N	N	N	N	N	N	N	N	N	Y	N	N	N	Y	Y	N	Y	N	11	2.3	N	N
77	546081	77	S	27	HW	PR	2	4	2	0	1	25	143	41	20.09	82	108	72	n	9.7	727	700	4	N	N	N	N	N	N	N	N	N	N	N	Y	N	N	N	N	N	N	12.1	2.4	N	N
78	546356	78	S	20	HW	RW	3	2	-	-	1	25	156	52	21.30	78	116	70	n	9.1	737	700	4	N	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11	1.9	N	N
79	545636	79	C	24	HW	PR	2	2	1	1	-	34	154	50	21.09	86	112	80	n	9.9	632	600	1	N	N	N	N	N	N	N	Y	Y	N	N	N	N	N	N	N	N	12	2.1	N	N
80	549059	80	S	19	HW	RW	3	1	-	-	-	33	155	57	23.70	80	110	70	n	8.6	828	850	4	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.5	1.9	N	N
81	549384	81	S	28	HW	RW	3	2	1	0	-	26	152	62	27.19	80	118	70	n	8.3	900	900	4	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.5	2.2	N	N
82	550026	82	S	25	HW	PR	3	3	1	1	1	32	156	69	28.30	80	108	70	n	9.4	764	800	4	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11	1.6	N	N
83	549929	83	C	27	HW	PR	4	4	3	1	-	30	154	53	23.04	72	108	76	n	9.8	656	600	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.6	1.8	N	N
84	550394	84	C	20	HW	PR	2	1	-	-	-	34	151	59	25.87	86	120	80	n	8.7	825	800	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.6	1.8	N	N
85	550096	85	C	27	HW	RW	4	4	3	3	-	34	155	57	23.75	85	114	76	n	7.2	1019	1000	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	9.4	2.2	N	N
86	550822	86	S	20	HW	PR	3	2	1	0	0	28	157	60	24.39	80	112	80	n	9.2	759.2	800	4	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.3	2.1	N	N
87	551394	87	C	27	HW	PR	3	4	2	1	1	21	158	45	18.07	76	108	70	n	9	716	700	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.3	2.3	N	N
88	551083	88	S	28	HW	PR	3	3	2	2	-	35	160	67	26.14	80	120	78	n	9.6	725	80	4	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.6	2	N	N
89	550634	89	S	22	HW	PR	4	2	1	1	-	24	166	63	22.90	78	112	70	n	9.8	681	700	4	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.5	1.7	N	N
90	550838	90	C	21	HW	PR	3	2	1	1	-	22	163	58	22.05	80	112	74	n	9.6	694	700	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.7	2.1	N	N
91	551886	91	C	23	HW	RW	3	1	-	-	-	35	160	77	30.08	80	110	86	n	9.8	721	700	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.2	1.4	N	N
92	552020	92	S	21	W	RW	3	1	-	-	-	33	158	55	22.03	80	108	70	n	9.6	684	700	3	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.8	2.2	N	N
93	551083	93	S	28	HW	RW	2	3	2	2	-	32	158	68	27.24	86	106	68	n	9.3	777	700	3	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.4	2.1	N	N
94	551826	94	C	22	HW	RW	2	1	-	-	-	34	154	53	22.35	82	106	74	n	8.9	805	800	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.2	2.3	N	N
95	550553	95	C	27	W	IL	4	2	-	-	1	35	160	54	21.09	78	112	86	n	8.4	836	800	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.4	2	N	N
96	551569	96	C	25	W	RW	3	3	2	2	-	34	170	61	21.11	84	110	80	n	7	1085	1000	1	N	Y	N	N	N	N	N	N	Y	N	N	N	N	N	N	N	N	9.6	2.6	N	N

ANNEXURE III - MASTER CHART

Serial Number	In Patient Number	Randomization Number	Group	Age (Years)	Demographic data			Obstetric score				Period of gestation (weeks)	Examination							Pre treatment haemoglobin (gm%)	Parenteral iron transfusion			Adverse effects																										Post treatment			Withdrawal from study
																	BP							Hypersensitivity reaction	Headache	Dizziness	Parasthesia	Hypotension	Hypertension	Flushing	Dyspnea	Nausea	Abdominal pain	Constipation	Diarrhoea	Administrative site reactions	Myalgia	Pyrexia	Chest pain	Rigors	Death				
					Occupation	Education	Socio economic status	Gravida	Para	Living	Abortion		Height (Cms)	Weight (Kgs)	BMI (Kg/m^2)	Pulse rate (per minute)	Systolic (mm Hg)	Diastolic (mm Hg)	Systemic examination		Required dose (mg)	Doses (mg)	Number of Infusions																					Haemoglobin (gm%)	Rise in haemoglobin (gm%)	Blood transfusion	
97	551036	97	C	29	W	RW	2	2	1	1	-	32	160	68	26.56	80	108	78	n	7.6	1054	1000	1	N	N	N	N	Y	N	N	N	Y	N	N	N	N	N	N	N	N	N	10.9	3.1	N	N
98	550060	98	S	20	HW	RW	3	1	-	-	-	35	154	44	18.55	72	102	70	n	11	552	600	3	N	N	N	N	N	N	N	N	Y	N	N	N	Y	N	N	N	N	N	12.6	2.1	N	N
99	551044	99	C	24	HW	RW	3	2	1	1	-	32	156	54	22.19	78	120	82	n	9.4	836	800	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.7	2.3	N	N
100	551072	100	C	24	W	RW	3	3	1	1	1	21	155	57	23.73	80	110	76	n	10	595	600	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	13.2	2.9	N	N
101	554750	101	S	27	W	RW	3	3	2	2	-	33	162	58	22.10	76	118	72	n	9.8	667	700	3	N	N	N	N	N	N	N	N	N	Y	N	N	N	N	N	N	N	N	11.9	2.1	N	N
102	554747	102	C	21	HW	RW	2	1	-	-	-	32	160	52	20.31	80	112	70	n	8.2	849	800	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.7	2.5	N	N
103	554752	103	C	22	HW	PR	2	1	-	-	-	32	157	72	29.21	84	116	70	n	9.2	811	800	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.6	2.4	N	N
104	554702	104	C	23	HW	RW	1	2	1	1	-	33	154	50	21.08	80	108	72	n	9.6	668	600	1	N	N	N	N	N	N	N	N	N	N	Y	N	N	N	N	N	N	N	11.7	2.1	N	N
105	554056	105	C	27	HW	PR	2	2	1	1	-	31	167	58	20.80	86	110	70	n	8.7	806	800	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.1	2.4	N	N
106	556682	106	C	22	HW	RW	3	2	1	0	-	34	158	60	24.03	80	112	80	n	8.8	816	800	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.9	2.1	N	N
107	556972	107	C	23	W	RW	3	1	-	-	-	16	152	56	24.24	70	108	72	n	8.1	889	800	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.9	2.8	N	N
108	555701	108	S	28	W	SC	2	2	1	-	-	32	163	55	20.70	80	110	80	n	9.2	737	700	3	N	N	N	N	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	11.3	2.1	N	N
109	557004	109	C	25	HW	IL	3	3	2	2	-	34	160	58	22.66	78	112	70	n	9	778	800	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	Y	N	N	N	11.2	2.2	N	N
110	556502	110	C	19	HW	PR	1	1	-	-	-	18	163	44	16.56	80	116	80	n	8.2	795	800	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.5	2.3	N	N
111	556223	111	S	23	HW	RW	3	2	1	1	-	32	155	48	19.98	74	120	80	n	8.6	776	800	4	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.5	1.9	N	N
112	553143	112	S	19	HW	RW	4	1	-	-	-	31	172	70	23.66	82	110	80	n	9.6	735	700	3	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.7	2.1	N	N
113	558399	113	S	28	HW	RW	3	4	1	1	2	32	166	75	27.22	86	122	80	n	9.2	810	800	4	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-	-	-	Y
114	557809	114	C	19	HW	RW	3	1	-	-	-	31	168	53	18.78	78	108	80	n	8.7	801	800	1	N	N	N	N	N	N	N	N	N	N	N	N	N	Y	Y	N	N	N	10.8	2.1	N	N
115	558236	115	S	28	HW	PR	2	3	2	1	-	32	149	52	23.42	78	120	80	n	8.8	763	800	4	N	N	N	Y	N	N	N	N	Y	Y	N	N	N	N	N	N	N	N	10.5	1.8	N	N
116	558152	116	S	21	HW	RW	2	2	1	1	-	33	155	44	18.31	82	116	76	n	9.1	701	700	4	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11	1.9	N	N
117	550383	117	S	20	HW	GR	2	1	-	-	-	32	167	60	21.51	82	118	72	n	8.5	845	800	4	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.5	2	N	N
118	555820	118	S	29	W	GR	1	2	-	-	1	34	148	46	21.00	86	110	70	n	9.3	679	700	4	N	N	N	N	N	N	N	N	N	N	N	N	N	Y	N	N	N	N	11.4	2.1	N	N
119	555869	119	S	26	HW	PR	1	3	2	2	-	30	156	58	23.83	72	108	72	n	7.8	926	900	5	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.1	2.3	N	N
120	555891	120	S	30	HW	SC	1	2	1	1	-	28	160	52	20.31	78	120	80	n	8.3	822	800	4	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.4	2.1	N	N
121	556099	121	C	23	HW	SC	1	2	1	0	-	33	158	51	20.43	76	112	78	n	9.2	711	700	1	N	N	N	Y	N	N	N	N	N	N	N	N	N	Y	N	N	N	N	11.3	2.1	N	N
122	556022	122	C	30	HW	SC	2	2	1	1	-	32	162	58	22.10	76	126	80	n	8.6	820	800	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.8	2.2	N	N
123	555948	123	S	23	W	GR	1	1	-	-	-	29	167	61	21.87	86	122	88	n	8.2	892	900	5	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	9.9	1.7	N	N
124	556191	124	C	21	HW	RW	3	1	-	-	-	34	168	57	20.20	78	110	70	n	9.3	722	700	1	N	Y	N	N	N	N	N	N	N	Y	N	N	N	N	N	N	N	N	11.1	1.8	N	N
125	556312	125	C	30	HW	PR	2	1	-	-	-	33	157	42	17.04	72	108	70	n	8.8	712	700	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.9	2.1	N	N
126	556323	126	S	22	W	GR	1	1	-	-	-	28	160	52	20.31	86	118	78	n	9.2	715	700	4	N	N	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.1	1.9	N	N
127	556512	127	S	31	HW	RW	3	2	1	1	-	29	157	41	16.63	80	120	82	n	8.5	735	700	4	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.7	2.2	N	N
128	556720	128	C	25	HW	IL	3	2	1	1	-	31	162	46	17.53	72	112	70	n	9.4	769	800	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.2	1.8	N	N

ANNEXURE III - MASTER CHART

Serial Number	In Patient Number	Randomization Number	Group	Age (Years)	Demographic data			Obstetric score				Period of gestation (weeks)	Examination							Pre treatment haemoglobin (gm%)	Parenteral iron transfusion			Adverse effects																												Post treatment			Withdrawal from study
																	BP																																				
					Occupation	Education	Socio economic status	Gravida	Para	Living	Abortion		Height (Cms)	Weight (Kgs)	BMI (Kg/m^2)	Pulse rate (per minute)	Systolic (mm Hg)	Diastolic (mm Hg)	Systemic examination		Required dose (mg)	Doses (mg)	Number of Infusions	Hypersensitivity reaction	Headache	Dizziness	Parasthesia	Hypotension	Hypertension	Flushing	Dyspnea	Nausea	Abdominal pain	Constipation	Diarrhoea	Administrative site reactions	Myalgia	Pyrexia	Chest pain	Rigors	Death	Haemoglobin (gm%)	Rise in haemoglobin (gm%)	Blood transfusion	
129	556756	129	C	28	HW	GR	1	2	1	1	-	31	159	40	15.82	70	102	70	n	9	784	800	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.1	2.1	N	N
130	556854	130	S	27	HW	PR	1	1	-	-	-	30	168	62	21.97	86	124	88	n	7.8	956	1000	5	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10	2.3	N	N
131	557181	131	S	23	HW	IL	3	3	1	1	1	34	156	42	17.26	80	122	80	n	8.1	793	800	4	N	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	9.9	1.8	N	N
132	557181	132	C	25	HW	GR	1	2	1	1	-	28	163	46	17.31	76	110	78	n	9.7	737	700	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.5	1.8	N	N
133	557533	133	C	23	HW	PR	2	1	-	-	-	30	171	66	22.57	80	116	80	n	8.3	909	900	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.6	2.3	N	N
134	557826	134	C	27	HW	PR	2	2	1	1	-	29	158	47	18.83	72	118	80	n	7.9	835	800	1	N	N	N	N	N	N	N	N	N	N	N	N	N	Y	N	N	N	10	2.1	N	N
135	557651	135	C	28	W	IL	4	1	-	-	-	31	152	44	19.04	70	100	72	n	9.4	761	700	4	N	N	N	N	N	N	N	N	N	N	N	N	N	Y	N	N	N	11.5	2.1	N	N
136	557823	136	S	32	HW	SC	2	2	1	1	-	32	160	47	18.36	82	116	80	n	9.9	718	700	4	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.7	1.8	N	N
137	557910	137	S	20	HW	RW	2	1	-	-	-	33	158	56	22.43	76	110	70	n	8.8	783	800	4	N	N	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.9	2.1	N	N
138	557956	138	S	33	W	GR	1	2	1	1	-	34	159	60	23.73	86	122	84	n	7.9	927	1000	5	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.2	2.3	N	N
139	558337	139	S	20	HW	PR	2	2	-	-	1	29	138	40	21.00	72	116	80	n	10	564	600	3	N	N	Y	N	N	N	N	N	N	Y	N	N	N	N	N	N	N	N	12	1.7	N	N
140	558420	140	S	22	W	SC	1	2	1	1	-	33	158	49	19.63	72	110	70	n	9.5	769	800	4	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.3	1.8	N	N
141	561235	141	S	21	HW	SC	1	1	-	-	-	34	148	52	23.74	80	110	82	n	9.2	715	700	3	N	N	N	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11	1.8	N	N
142	561123	142	C	26	W	SC	1	1	-	-	-	32	168	68	24.09	76	122	80	n	7.8	1000	1000	1	N	N	N	N	N	N	N	N	N	N	N	Y	N	N	N	N	Y	N	10	2.2	N	N
143	561208	143	C	29	HW	PR	1	4	1	1	2	35	146	54	25.33	78	112	70	n	8.7	785	800	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.5	1.8	N	N
144	561266	144	S	36	W	RW	2	1	-	-	-	30	161	57	21.99	84	112	80	n	9.3	722	700	3	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.2	1.9	N	N
145	561369	145	C	30	HW	PR	1	2	1	1	-	34	160	56	21.88	78	116	74	n	9.1	744	700	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.9	1.8	N	N
146	561449	146	S	26	HW	PR	1	4	2	1	1	33	142	46	22.81	74	108	78	n	8.8	732	700	3	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.9	2.1	N	N
147	561614	147	C	34	HW	RW	3	4	3	1	-	34	152	43	18.61	84	122	86	n	9	697	700	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11	2	N	N
148	561699	148	C	22	W	RW	3	1	-	-	-	29	148	53	24.20	84	106	72	n	10	597	600	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-	-	-	Y
149	561854	149	C	27	W	IL	3	2	1	1	-	33	157	56	22.72	74	116	80	n	8.7	796	800	1	N	Y	N	N	N	N	N	N	Y	N	N	N	Y	N	N	N	N	N	10.5	1.8	N	N
150	561729	150	S	28	W	RW	2	2	1	1	-	34	160	48	18.75	74	106	74	n	9.9	621	600	3	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	12	2.1	N	N
151	561665	151	S	19	HW	PR	1	1	-	-	-	33	170	62	21.45	80	110	80	n	8.9	799	800	4	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11	2.1	N	N
152	561934	152	S	23	HW	PR	2	4	1	1	2	35	147	56	25.92	78	112	80	n	9.3	718	700	3	N	N	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.1	1.8	N	N
153	562122	153	C	25	HW	PR	2	4	2	2	1	32	152	50	21.64	76	102	74	n	10	580	600	1	N	N	N	N	N	N	N	N	Y	N	N	N	N	Y	N	N	N	N	12	1.7	N	N
154	562317	154	C	28	W	RW	3	2	1	1	-	33	160	57	22.27	80	110	70	n	9.7	670	700	1	N	N	N	N	N	N	N	N	N	N	N	N	N	Y	N	N	N	N	12	2.3	N	N
155	562294	155	S	34	HW	RW	1	3	1	1	1	34	163	61	22.96	86	112	80	n	11	570	600	3	N	N	N	N	N	N	N	N	N	N	Y	N	N	N	N	N	N	N	12	1.5	N	N
156	562554	156	C	30	HW	RW	2	2	1	1	-	32	168	58	20.55	76	126	84	n	8.5	833	800	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.6	2.1	N	N
157	562611	157	C	27	HW	SC	1	2	1	1	-	32	170	68	23.53	70	110	72	n	10	640	600	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.7	1.6	N	N
158	562518	158	S	25	W	IL	3	1	-	-	-	33	152	48	20.78	80	112	80	n	8.2	8.9	800	4	N	N	N	N	N	N	N	N	N	N	N	N	N	Y	N	N	N	-	-	-	Y
159	562472	159	S	36	HW	PR	1	2	1	1	-	32	166	58	21.05	76	118	72	n	9.4	713	700	3	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.5	2.1	N	N
160	562697	160	C	26	W	RW	2	1	-	-	-	34	162	57	21.72	80	122	80	n	9	762	700	1	N	N	N	N	N	N	N	N	N	N	N	N	N	Y	N	N	N	11.3	2.3	N	N

ANNEXURE III - MASTER CHART

Serial Number	In Patient Number	Randomization Number	Group	Age (Years)	Demographic data			Obstetric score				Period of gestation (weeks)	Examination							Pre treatment haemoglobin (gm%)	Parenteral iron transfusion			Adverse effects																										Post treatment			Withdrawal from study
																	BP							Hypersensitivity reaction	Headache	Dizziness	Parasthesia	Hypotension	Hypertension	Flushing	Dyspnea	Nausea	Abdominal pain	Constipation	Diarrhoea	Administrative site reactions	Myalgia	Pyrexia	Chest pain	Rigors	Death				
					Occupation	Education	Socio economic status	Gravida	Para	Living	Abortion		Height (Cms)	Weight (Kgs)	BMI (Kg/m^2)	Pulse rate (per minute)	Systolic (mm Hg)	Diastolic (mm Hg)	Systemic examination		Required dose (mg)	Doses (mg)	Number of Infusions																					Haemoglobin (gm%)	Rise in haemoglobin (gm%)	Blood transfusion	
161	562812	161	S	29	W	SC	1	1	-	-	-	34	148	48	21.91	80	112	80	n	8.6	776	800	4	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.3	1.7	N	N
162	562892	162	S	25	HW	RW	2	2	-	-	1	32	155	53	22.06	76	110	70	n	9.4	703	700	3	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.5	2.1	N	N
163	572316	163	S	30	HW	SC	1	3	1	1	-	30	159	55	21.76	86	116	84	n	10	605	600	3	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	12	1.8	N	N
164	572515	164	C	29	W	PR	1	3	-	-	2	32	167	54	19.36	80	122	84	n	9	759	700	1	N	N	N	N	N	N	N	N	N	Y	N	N	N	N	N	N	N	N	N	11	2.4	N	N
165	572711	165	S	24	HW	RW	2	1	-	-	-	29	148	45	20.54	82	110	76	n	9.6	651	600	3	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.7	2.1	N	N
166	572233	166	S	24	HW	PR	1	2	-	-	1	30	152	52	22.51	78	110	70	n	8.9	762	700	3	N	N	N	N	N	N	N	N	N	N	N	N	Y	N	N	N	N	N	N	11.5	1.6	N	N
167	572955	167	S	21	W	SC	1	1	-	-	-	33	162	60	22.86	86	124	76	n	9.5	716	700	3	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.6	2.1	N	N
168	573086	168	S	19	HW	RW	2	1	-	-	-	31	154	56	23.61	80	116	80	n	10	580	600	3	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	12.1	1.7	N	N
169	572985	169	C	29	W	RW	3	4	3	3	-	31	160	58	22.66	78	118	70	n	9.6	794	800	1	N	N	N	N	N	N	N	N	N	N	Y	N	N	N	N	N	N	N	N	11.2	1.7	N	N
170	573551	170	C	26	HW	IL	3	1	-	-	-	30	156	59	24.24	80	112	80	n	8.9	798	800	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11	2.1	N	N
171	573800	171	S	30	HW	RW	2	2	1	1	-	30	160	62	24.22	80	112	80	n	8.6	799	800	4	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-	-	-	DL
172	574141	172	S	23	W	PR	1	3	2	2	-	33	172	64	21.63	80	122	80	n	10	638	600	3	N	N	N	N	N	N	N	N	N	N	Y	N	N	N	N	N	N	N	N	12.3	2.2	N	N
173	574414	173	C	20	HW	RW	3	1	-	-	-	35	162	60	22.86	80	110	70	n	8.2	903	900	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.6	2.4	N	N
174	574473	174	C	26	HW	RW	2	3	1	1	1	34	172	68	22.99	82	112	80	n	9.7	712	700	1	N	N	N	N	N	N	N	N	Y	N	N	N	N	N	N	N	N	N	N	11.5	1.8	N	N
175	574414	175	C	26	HW	RW	2	2	1	1	-	33	157	49	19.88	84	108	70	n	9.6	764	700	1	N	N	N	N	N	N	N	N	Y	N	N	N	N	N	Y	N	N	N	N	11.2	1.6	N	N
176	574624	176	S	30	W	SC	1	1	-	-	-	28	142	40	19.84	76	112	80	n	9.8	715	700	3	N	N	N	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	12.2	2.4	N	N
177	575218	177	S	27	W	RW	2	2	1	1	-	29	152	46	19.91	80	122	76	n	11	544	500	3	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	12.9	2.3	N	N
178	578319	178	S	20	HW	PR	2	1	-	-	-	20	150	54	24.00	80	120	82	n	11	554	500	3	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	12.9	2.2	N	N
179	575225	179	C	25	W	RW	3	3	2	2	-	31	148	52	23.74	78	110	70	n	10	599	600	1	N	Y	Y	N	N	N	N	N	N	N	N	N	N	N	Y	N	N	N	12.6	2.4	N	N
180	575275	180	C	26	HW	RW	2	1	-	-	-	28	162	59	22.48	82	102	68	n	9.4	726	700	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.6	2.2	N	N
181	575831	181	C	27	HW	SC	1	1	-	-	-	28	156	51	20.96	80	112	70	n	11	558	600	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	12.9	2.4	N	N
182	574590	182	C	28	HW	RW	3	3	2	2	-	34	152	60	25.97	82	120	84	n	8.4	750	700	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.1	1.7	N	N
183	575805	183	S	23	HW	RW	3	2	1	1	-	18	150	54	24.00	78	122	80	n	7.1	984	1000	5	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	9.5	2.4	N	N
184	575173	184	C	23	HW	RW	3	2	1	1	-	30	154	50	21.08	78	110	72	n	7	960	1000	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	9.5	2.5	N	N
185	578355	185	C	26	HW	RW	3	1	-	-	-	20	160	50	19.53	82	110	70	n	11	557	500	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	12.2	1.7	N	N
186	578314	186	C	24	HW	RW	1	2	1	1	-	20	156	42	17.26	76	102	68	n	7.3	857	800	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	9.5	2.2	N	N
187	578707	187	C	28	HW	IL	2	3	2	2	-	25	160	51	19.92	88	120	86	n	8.3	816	800	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.7	2.4	N	N
188	578305	188	S	19	HW	PR	2	1	-	-	-	27	151	50	21.93	82	120	76	n	11	546	500	3	N	N	N	N	N	N	N	N	N	Y	N	N	N	Y	N	N	Y	N	N	12.7	2.1	N	N
189	575756	189	C	20	HW	RW	3	1	-	-	-	28	162	55	20.96	80	110	70	n	8.6	816	800	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	Y	N	N	10.7	2.1	N	N
190	580145	190	C	32	HW	IL	2	2	1	1	-	29	142	58	28.76	84	110	80	n	8.3	875	800	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.8	2.5	N	N
191	580806	191	C	22	W	SC	1	1	-	-	-	34	168	62	21.97	80	108	78	n	9.3	752	700	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	Y	N	11.9	2.6	N	N
192	580502	192	C	24	HW	RW	3	3	2	2	-	27	152	48	20.78	72	102	70	n	8.6	776	800	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.1	2.5	N	N

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Serial Number	In Patient Number	Randomization Number	Group	Age (Years)	Demographic data			Obstetric score				Period of gestation (weeks)	Examination							Pre treatment haemoglobin (gm%)	Parenteral iron transfusion			Adverse effects																												Post treatment			Withdrawal from study
																	BP							Hypersensitivity reaction	Headache	Dizziness	Parasthesia	Hypotension	Hypertension	Flushing	Dyspnea	Nausea	Abdominal pain	Constipation	Diarrhoea	Administrative site reactions	Myalgia	Pyrexia	Chest pain	Rigors	Death				
					Occupation	Education	Socio economic status	Gravida	Para	Living	Abortion		Height (Cms)	Weight (Kgs)	BMI (Kg/m^2)	Pulse rate (per minute)	Systolic (mm Hg)	Diastolic (mm Hg)	Systemic examination		Required dose (mg)	Doses (mg)	Number of Infusions																						Haemoglobin (gm%)	Rise in haemoglobin (gm%)	Blood transfusion	
193	580529	193	C	23	W	IL	3	2	1	1	-	30	158	51	20.43	78	120	82	n	9.1	732	700	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.7	2.6	N	N
194	580784	194	C	34	W	RW	2	3	1	1	1	31	155	56	23.31	80	110	76	n	8.6	822	800	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.4	2.8	N	N
195	581084	195	S	32	HW	RW	1	1	-	-	-	33	150	48	21.33	76	118	72	n	9.8	636	600	3	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	12	2.2	N	N
196	581145	196	S	23	W	RW	2	3	1	1	1	28	160	58	22.66	80	112	70	n	8.2	889	900	5	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10	1.8	N	N
197	581324	197	C	25	W	IL	3	2	1	1	-	29	164	57	21.19	84	116	70	n	7.6	965	1000	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10	2.4	N	N
198	581513	198	S	26	W	RW	3	4	2	2	1	28	148	40	18.26	80	108	72	n	7.9	797	800	4	N	N	N	N	N	N	N	N	N	N	N	Y	N	Y	N	N	N	N	11	2.1	N	N
199	585016	199	S	21	HW	PR	2	1	-	-	-	25	156	49	20.13	86	110	70	n	8.3	900	900	5	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.5	2.5	N	N
200	585345	200	C	28	W	RW	3	3	2	2	-	23	158	59	23.63	70	108	72	n	8.9	797	800	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.6	1.7	N	N
201	584222	201	S	19	HW	RW	3	1	-	-	-	29	146	55	25.80	80	110	80	n	8	897	900	4	N	Y	N	N	N	N	N	N	Y	N	N	N	N	N	N	N	N	N	N	10.3	2.3	N	N
202	585367	202	C	26	W	RW	3	3	2	2	-	24	148	42	19.17	78	112	70	n	7.5	850	800	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.1	2.6	N	N
203	585753	203	C	30	HW	RW	2	3	1	1	1	35	165	80	29.38	80	116	80	n	8.8	1114	1000	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.6	1.8	N	N
204	586335	204	C	24	HW	RW	3	2	1	1	-	34	152	55	23.81	74	120	80	n	7.5	1026	1000	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	9.7	2.2	N	N
205	581518	205	C	24	HW	IL	1	2	1	1	-	29	157	51	20.69	82	110	80	n	8.7	781	700	1	N	Y	N	N	N	N	N	N	Y	N	N	N	N	N	N	N	N	N	N	11	2.3	N	N
206	581845	206	C	28	W	RW	3	3	2	2	-	33	168	58	20.55	86	122	80	n	7.8	945	900	2	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10	2.2	N	N
207	581878	207	C	25	HW	RW	3	2	1	1	-	30	155	46	19.15	78	108	80	n	9.3	687	700	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.1	1.8	N	N
208	582052	208	C	29	W	RW	3	3	2	2	-	31	148	42	19.17	80	112	80	n	8.9	711	700	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.3	2.4	N	N
209	586481	209	S	20	HW	RW	2	1	-	-	-	29	150	46	20.44	76	118	72	n	7.8	853	800	4	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10	2.2	N	N
210	582669	210	S	29	W	RW	2	4	2	2	1	33	164	60	22.31	80	122	80	n	8.9	802	800	4	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.8	1.9	N	N
211	582385	211	S	24	W	RW	3	2	1	1	-	26	157	53	21.50	80	112	80	n	9.3	716	700	4	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.5	2.2	N	N
212	582731	212	S	26	HW	PR	4	1	3	2	2	32	158	49	19.63	76	110	70	n	9.1	723	700	4	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11	1.9	N	N
213	582698	213	C	26	HW	RW	3	1	-	-	-	32	160	52	20.31	86	116	84	n	9.7	762	700	1	N	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	12	2.3	N	N
214	582967	214	S	29	W	RW	2	2	1	1	-	29	147	42	19.44	80	122	84	n	8.3	772	800	4	N	N	N	N	N	N	N	N	N	N	N	N	N	Y	N	N	N	N	N	N	10	1.7	N	N
215	583016	215	C	24	HW	RW	2	3	1	1	1	34	156	50	20.55	82	110	76	n	7.9	872	800	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.4	2.5	N	N
216	583027	216	C	21	W	RW	3	2	1	1	-	34	164	58	21.56	78	110	70	n	8.5	835	800	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.9	2.4	N	N
217	583347	217	C	23	W	IL	2	3	1	1	1	26	152	56	24.24	86	124	76	n	8.2	876	800	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.5	2.3	N	N
218	583363	218	S	24	HW	RW	1	2	1	1	-	29	168	59	20.90	80	116	80	n	9.5	712	700	4	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.2	1.7	N	N
219	`583756	219	S	20	W	IL	3	1	-	-	-	32	159	60	23.73	78	118	70	n	9.7	687	700	4	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.5	1.8	N	N
220	584096	220	S	30	W	SC	1	2	1	1	-	33	168	70	24.80	80	112	80	n	9.2	802	800	4	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11	1.8	N	N
221	584080	221	S	27	W	RW	3	3	1	1	1	31	155	55	22.89	80	112	80	n	8.1	882	800	4	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-	-	-	Y
222	593846	222	C	30	W	IL	3	4	2	2	1	34	162	48	18.29	80	122	80	n	8	845	800	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.6	2.6	N	N
223	584906	223	S	24	W	RW	4	4	1	1	2	28	152	49	21.21	80	110	70	n	8.6	782	800	4	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-	-	-	Y
224	585139	224	C	28	W	RW	3	2	1	1	-	29	163	57	21.45	82	112	80	n	9	773	700	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.3	2.3	N	N

ANNEXURE III - MASTER CHART

					Demographic data			Obstetric score					Examination				BP				Parenteral iron transfusion			Adverse effects																		Post treatment			
Serial Number	In Patient Number	Randomization Number	Group	Age (Years)	Occupation	Education	Socio economic status	Gravida	Para	Living	Abortion	Period of gestation (weeks)	Height (Cms)	Weight (Kgs)	BMI (Kg/m^2)	Pulse rate (per minute)	Systolic (mm Hg)	Diastolic (mm Hg)	Systemic examination	Pre treatment haemoglobin (gm%)	Required dose (mg)	Doses (mg)	Number of Infusions	Hypersensitivity reaction	Headache	Dizziness	Parasthesia	Hypotension	Hypertension	Flushing	Dyspnea	Nausea	Abdominal pain	Constipation	Diarrhoea	Administrative site reactions	Myalgia	Pyrexia	Chest pain	Rigors	Death	Haemoglobin (gm%)	Rise in haemoglobin (gm%)	Blood transfusion	Withdrawal from study
225	585421	225	S	29	W	IL	3	3	1	1	1	29	159	56	22.15	84	108	70	n	9.5	836	800	4	N	Y	N	N	N	N	N	N	N	N	N	N	N	N	Y	N	N	N	11.1	1.6	N	N
226	585428	226	C	30	HW	RW	2	2	1	1	-	31	156	58	23.83	76	112	80	n	7.6	973	1000	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.1	2.5	N	N
227	585603	227	S	23	HW	RW	3	2	-	-	1	33	168	70	24.80	80	122	84	n	9.2	970	1000	5	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11	1.8	N	N
228	585756	228	S	22	W	RW	3	3	1	1	1	23	160	55	21.48	82	110	76	n	8.9	777	800	4	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-	-	-	Y
229	582677	229	C	24	W	RW	4	3	2	2	-	31	156	52	21.37	78	110	70	n	9	749	700	1	N	N	N	N	N	N	N	N	N	N	N	N	N	Y	N	N	N	N	11.3	2.3	N	N
230	585976	230	S	26	HW	PR	1	2	1	1	-	28	172	72	24.34	86	124	76	n	8.8	880	800	4	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.5	1.7	N	N
231	586028	231	C	22	W	RW	3	3	1	1	1	32	157	48	19.47	80	116	80	n	10	597	600	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	12.5	2.2	N	N
232	586236	232	S	20	HW	PR	1	1	-	-	-	29	162	59	22.48	82	102	68	n	7.6	981	1000	5	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	9.9	2.2	N	N
233	586029	233	C	29	W	IL	3	3	2	2	-	26	149	45	20.27	80	112	70	n	9.2	794	800	4	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11	1.8	N	N
234	586673	234	C	28	W	RW	3	2	1	1	-	28	158	62	24.84	82	120	84	n	8	946	1000	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-	-	-	Y
235	587328	235	C	20	W	PR	1	2	1	1	-	30	160	55	21.48	78	122	80	n	9.3	724	700	1	N	N	Y	N	N	N	N	N	N	N	N	N	Y	N	N	N	N	N	11.6	2.3	N	N
236	587564	236	S	25	HW	RW	2	1	-	-	-	30	158	52	20.83	78	110	72	n	7.9	886	900	5	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10	2.1	N	N
237	588220	237	S	25	W	IL	3	3	2	2	-	34	166	74	26.85	72	110	70	n	9	855	800	4	N	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.7	1.7	N	N
238	588230	238	S	27	W	RW	2	3	2	2	-	27	154	48	20.24	82	110	76	n	8.7	764	700	4	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.5	1.8	N	N
239	593735	239	S	25	W	RW	2	3	2	1	-	34	152	58	25.10	80	120	80	n	7.6	973	1000	5	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.5	2.9	N	N
240	593825	240	S	20	W	PR	2	1	-	-	-	32	160	53	20.70	76	110	78	n	8.2	856	800	4	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.1	2.9	N	N
241	590911	241	S	26	HW	PR	3	2	1	1	-	33	160	42	15.62	80	126	80	n	8.4	762	800	4	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11	2.6	N	N
242	593946	242	S	19	HW	RW	1	1	-	-	-	35	158	54	21.68	86	120	80	n	9.1	746	800	4	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.8	2.7	N	N
243	593872	243	C	22	HW	PR	3	1	-	-	-	34	164	48	17.90	86	110	80	n	7.6	891	880	1	N	N	N	N	N	N	N	N	N	N	N	N	N	Y	N	N	N	N	9.9	2.3	N	N
244	594255	244	S	22	HW	RW	3	1	0	0	-	33	158	40	16.06	92	110	76	n	8.8	742	800	4	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.8	2	N	N
245	594391	245	C	28	W	RW	3	2	1	1	-	29	163	57	21.45	82	112	80	n	9	773	700	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.3	2.3	N	N
246	594885	246	S	29	W	IL	3	3	1	1	1	29	159	56	22.15	84	108	70	n	9.5	836	800	4	N	N	N	N	N	N	N	N	N	N	N	N	N	N	Y	N	N	N	11.1	1.6	N	N
247	594364	247	C	30	HW	RW	2	2	1	1	-	31	156	58	23.83	76	112	80	n	7.6	973	1000	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.1	2.5	N	N
248	595154	248	S	23	HW	RW	3	2	-	-	1	33	168	70	24.80	80	122	84	n	9.2	970	1000	5	N	N	N	N	N	N	N	N	Y	N	N	N	N	N	N	N	N	N	11	1.8	N	N
249	594639	249	C	20	W	SC	1	1	-	-	-	34	168	62	21.97	80	108	78	n	9.3	752	700	1	N	N	N	N	N	N	N	N	N	N	Y	N	N	N	N	N	N	N	11.9	2.6	N	N
250	595105	250	C	24	HW	RW	3	3	2	2	-	27	152	48	20.78	72	102	70	n	8.6	776	800	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.1	2.5	N	N
251	595116	251	C	23	W	IL	3	2	1	1	-	30	158	51	20.43	78	120	82	n	9.1	732	700	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.7	2.6	N	N
252	595124	252	C	34	W	RW	2	3	1	1	1	31	155	56	23.31	80	110	76	n	8.6	822	800	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.4	2.8	N	N
253	595410	253	S	32	HW	RW	1	1	-	-	-	33	150	48	21.33	76	118	72	n	9.8	636	600	3	N	N	Y	N	N	N	N	N	Y	N	N	N	N	N	N	N	Y	N	12	2.2	N	N
254	595498	254	S	23	W	RW	2	3	1	1	1	28	160	58	22.66	80	112	70	n	8.2	889	900	5	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10	1.8	N	N
255	595763	255	C	25	W	IL	3	2	1	1	-	29	164	57	21.19	84	116	70	n	7.6	965	1000	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	Y	N	N	N	10	2.4	N	N
256	595731	256	S	26	W	RW	3	4	2	2	1	28	148	40	18.26	80	108	72	n	7.9	797	800	4	N	N	Y	N	N	N	N	N	N	Y	N	N	N	N	N	N	N	N	11	2.1	N	N

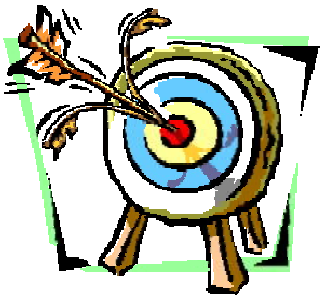
ANNEXURE III - MASTER CHART

Serial Number	In Patient Number	Randomization Number	Group	Age (Years)	Demographic data			Obstetric score				Period of gestation (weeks)	Examination							Pre treatment haemoglobin (gm%)	Parenteral iron transfusion			Adverse effects																										Post treatment			Withdrawal from study
																	BP							Hypersensitivity reaction	Headache	Dizziness	Parasthesia	Hypotension	Hypertension	Flushing	Dyspnea	Nausea	Abdominal pain	Constipation	Diarrhoea	Administrative site reactions	Myalgia	Pyrexia	Chest pain	Rigors	Death				
					Occupation	Education	Socio economic status	Gravida	Para	Living	Abortion		Height (Cms)	Weight (Kgs)	BMI (Kg/m^2)	Pulse rate (per minute)	Systolic (mm Hg)	Diastolic (mm Hg)	Systemic examination		Required dose (mg)	Doses (mg)	Number of Infusions																						Haemoglobin (gm%)	Rise in haemoglobin (gm%)	Blood transfusion	
257	595847	257	S	21	HW	PR	2	1	-	-	-	25	156	49	20.13	86	110	70	n	8.3	900	900	5	N	N	N	N	N	N	N	N	N	N	N	Y	N	N	N	N	N	10.5	2.5	N	N
258	595845	258	C	28	HW	PR	2	1	-	-	-	30	158	50	20.08	80	110	70	n	8.1	800	800	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.2	3.1	N	N
259	596044	259	S	19	HW	PR	2	1	-	-	-	35	152	48	20.77	80	110	70	n	8.9	700	700	4	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.4	2.5	N	N
260	595750	260	S	22	W	RW	3	1	-	-	-	30	152	54	23.47	80	126	80	n	8.9	700	700	4	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.1	2.3	N	N
261	596292	261	S	25	W	IL	2	2	-	-	1	28	152	59	24.68	76	110	70	n	7.6	981	1000	5	N	N	N	N	N	N	N	N	N	Y	N	N	N	N	N	N	N	10.4	2.8	N	N
262	595568	262	C	20	HW	PR	1	1	-	-	-	26	153	56	23.93	80	116	80	n	8.5	836	1000	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.8	2.2	N	N
263	596381	263	C	21	HW	PR	1	1	-	-	-	33	164	57	21.20	86	112	78	n	9.5	705	700	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	12.3	2.8	N	N
264	596757	264	C	22	W	RW	3	3	1	1	1	32	157	48	19.47	80	116	80	n	10	597	600	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	12.5	2.2	N	N
265	596287	265	S	26	HW	PR	1	1	-	-	-	29	162	59	22.48	82	102	68	n	7.6	981	1000	5	N	N	N	N	N	N	N	N	N	N	N	N	N	Y	N	N	N	9.9	2.2	N	N
266	596941	266	C	29	W	IL	3	3	2	2	-	26	149	45	20.27	80	112	70	n	9.2	794	800	4	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11	1.8	N	N
267	597055	267	C	28	W	RW	3	2	1	1	-	28	158	62	24.84	82	120	84	n	8	946	1000	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-	-	-	Y
268	597102	268	C	20	W	PR	1	2	1	1	-	30	160	55	21.48	78	122	80	n	9.3	724	700	1	N	N	N	N	N	N	N	N	N	N	N	N	Y	N	Y	N	N	11.6	2.3	N	N
269	596998	269	S	25	HW	RW	2	1	-	-	-	30	158	52	20.83	78	110	72	n	7.9	886	900	5	N	N	N	N	N	N	N	N	N	N	N	Y	N	N	N	N	N	10	2.1	N	N
270	597194	270	S	25	W	IL	3	3	2	2	-	34	166	74	26.85	72	110	70	n	9	855	800	4	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.7	1.7	N	N
271	597419	271	S	27	W	RW	2	3	2	2	-	27	154	48	20.24	82	110	76	n	8.7	764	700	4	N	N	N	N	N	N	N	Y	N	N	N	N	N	N	N	N	N	10.5	1.8	N	N
272	597104	272	S	20	HW	RW	2	1	-	-	-	33	158	56	22.43	76	110	70	n	8.8	783	800	4	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.9	2.1	N	N
273	597507	273	S	33	W	GR	1	2	1	1	-	34	159	60	23.73	86	122	84	n	7.9	927	1000	5	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.2	2.3	N	N
274	597812	274	S	20	HW	PR	2	2	-	-	1	29	138	40	21.00	72	116	80	n	10	564	600	3	N	N	N	N	N	N	N	N	N	N	N	N	Y	N	N	N	N	12	1.7	N	N
275	598097	275	S	22	W	SC	1	2	1	1	-	33	158	49	19.63	72	110	70	n	9.5	769	800	4	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.3	1.8	N	N
276	598159	276	S	21	HW	SC	1	1	-	-	-	34	148	52	23.74	80	110	82	n	9.2	715	700	3	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11	1.8	N	N
277	598115	277	C	26	W	SC	1	1	-	-	-	32	168	68	24.09	76	122	80	n	7.8	1000	1000	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10	2.2	N	N
278	598003	278	C	29	HW	PR	1	4	1	1	2	35	146	54	25.33	78	112	70	n	8.7	785	800	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.5	1.8	N	N
279	598173	279	S	36	W	RW	2	1	-	-	-	30	161	57	21.99	84	112	80	n	9.3	722	700	3	N	N	N	N	N	N	N	N	N	N	N	N	Y	N	N	N	N	11.2	1.9	N	N
280	598158	280	C	30	HW	PR	1	2	1	1	-	34	160	56	21.88	78	116	74	n	9.1	744	700	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.9	1.8	N	N
281	598130	281	S	26	HW	PR	1	4	2	1	1	33	142	46	22.81	74	108	78	n	8.8	732	700	3	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.9	2.1	N	N
282	548425	282	C	34	HW	RW	3	4	3	1	-	34	152	43	18.61	84	122	86	n	9	697	700	1	N	N	N	N	N	N	N	N	N	N	N	N	N	Y	N	N	N	11	2	N	N
283	598284	283	C	22	W	RW	3	1	-	-	-	29	148	53	24.20	84	106	72	n	10	597	600	1	N	N	N	N	N	N	N	N	N	N	N	N	N	Y	N	N	N	-	-	-	Y
284	598510	284	C	25	W	IL	3	2	1	1	-	29	164	57	21.19	84	116	70	n	7.6	965	1000	1	N	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10	2.4	N	N
285	598602	285	S	26	W	RW	3	4	2	2	1	28	148	40	18.26	80	108	72	n	7.9	797	800	4	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11	2.1	N	N
286	598610	286	S	21	HW	PR	2	1	-	-	-	25	156	49	20.13	86	110	70	n	8.3	900	900	5	N	Y	Y	N	N	N	N	N	Y	N	N	N	N	N	N	N	N	10.5	2.5	N	N
287	598615	287	C	28	W	RW	3	3	2	2	-	23	158	59	23.63	70	108	72	n	8.9	797	800	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.6	1.7	N	N
288	598806	288	S	19	HW	RW	3	1	-	-	-	29	146	55	25.80	80	110	80	n	8	897	900	4	N	N	N	N	N	N	N	N	N	N	N	N	N	Y	N	N	N	10.3	2.3	N	N

ANNEXURE III - MASTER CHART

Serial Number	In Patient Number	Randomization Number	Group	Age (Years)	Demographic data			Obstetric score				Period of gestation (weeks)	Examination						Pre treatment haemoglobin (gm%)	Parenteral iron transfusion			Adverse effects																												Post treatment			Withdrawal from study
																	BP																																			
					Occupation	Education	Socio economic status	Gravida	Para	Living	Abortion		Height (Cms)	Weight (Kgs)	BMI (Kg/m^2)	Pulse rate (per minute)	Systolic (mm Hg)	Diastolic (mm Hg)	Systemic examination		Required dose (mg)	Doses (mg)	Number of Infusions	Hypersensitivity reaction	Headache	Dizziness	Parasthesia	Hypotension	Hypertension	Flushing	Dyspnea	Nausea	Abdominal pain	Constipation	Diarrhoea	Administrative site reactions	Myalgia	Pyrexia	Chest pain	Rigors	Death	Haemoglobin (gm%)	Rise in haemoglobin (gm%)	Blood transfusion	
289	598870	289	C	26	W	RW	3	3	2	2	-	24	148	42	19.17	78	112	70	n	7.5	850	800	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.1	2.6	N	N
290	599088	290	C	30	HW	RW	2	3	1	1	1	35	165	80	29.38	80	116	80	n	8.8	1114	1000	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.6	1.8	N	N
291	598682	291	C	24	HW	RW	3	2	1	1	-	34	152	55	23.81	74	120	80	n	7.5	1026	1000	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	9.7	2.2	N	N
292	598762	292	C	24	HW	IL	1	2	1	1	-	29	157	51	20.69	82	110	80	n	8.7	781	700	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11	2.3	N	N
293	599212	293	C	23	HW	RW	3	2	1	1	-	30	154	50	21.08	78	110	72	n	7	960	1000	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	9.5	2.5	N	N
294	599429	294	C	26	HW	RW	3	1	-	-	-	20	160	50	19.53	82	110	70	n	11	557	500	1	N	N	N	N	N	N	N	N	Y	N	N	N	N	N	N	N	N	N	12.2	1.7	N	N
295	599562	295	C	24	HW	RW	1	2	1	1	-	20	156	42	17.26	76	102	68	n	7.3	857	800	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	9.5	2.2	N	N
296	600080	296	C	28	HW	IL	2	3	2	2	-	25	160	51	19.92	88	120	86	n	8.3	816	800	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.7	2.4	N	N
297	600346	297	S	22	HW	PR	4	2	1	1	-	24	166	63	22.90	78	112	70	n	9.8	681	700	4	N	Y	N	N	N	N	N	N	Y	N	N	N	Y	Y	N	N	N	N	11.5	1.7	N	N
298	600377	298	C	21	HW	PR	1	2	1	1	-	22	163	58	22.05	80	112	74	n	9.6	694	700	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.7	2.1	N	N
299	600232	299	C	20	HW	RW	3	1	-	-	-	35	160	77	30.08	80	110	86	n	9.8	721	700	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.2	1.4	N	N
300	600518	300	S	21	W	RW	3	1	-	-	-	33	158	55	22.03	80	108	70	n	9.6	684	700	3	N	N	N	N	N	N	N	N	N	N	Y	N	N	N	N	N	N	N	11.8	2.2	N	N
301	600788	301	S	28	HW	RW	2	3	2	2	-	32	158	68	27.24	86	106	68	n	9.3	777	700	3	N	N	Y	N	N	N	N	N	Y	N	N	N	Y	Y	N	N	N	N	11.4	2.1	N	N
302	600642	302	C	19	HW	RW	2	1	-	-	-	34	154	53	22.35	82	106	74	n	8.9	805	800	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	11.2	2.3	N	N
303	600768	303	C	27	W	IL	4	2	-	-	1	35	160	54	21.09	78	112	86	n	8.4	836	800	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.4	2	N	N
304	601040	304	C	25	W	RW	3	3	2	2	-	34	170	61	21.11	84	110	80	n	7	956	1000	1	N	Y	N	N	N	N	N	N	Y	N	N	N	N	Y	N	N	N	N	9.6	2.6	N	N
305	601058	305	C	29	W	RW	2	2	1	1	-	32	160	68	26.56	80	108	78	n	7.6	985	1000	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	10.9	3.1	N	N

Introduction



Objectives

Review of Literature

Methodology

Results

Discussion

Conclusion

Summary

Bibliography

Annexure-I

Annexure-II

Annexure-III