# "ORAL CLINDAMYCIN FOR PREVENTION OF PRETERM LABOR IN PREGNANCIES OF 13 TO 16±1 WEEKS WITH VAGINAL PH ≥ 5 – A RANDOMIZED DOUBLE BLIND PLACEBO CONTROLLED TRIAL"


**By**

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# 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**

**Under the Guidance of**

**Dr. M. B. BELLAD** MD
**Professor**


**DEPARTMENT OF OBSTETRICS AND GYNAECOLOGY,**
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# LIST OF ABBREVIATIONS USED

| | | |
|---|---|---|
| APH | - | Antepartum hemorrhage |
| BMI | - | Body mass index |
| BV | - | Bacterial vaginosis |
| C | - | Clindamycin |
| CI | - | Confidence interval |
| Cms | - | Centimeters |
| DCI | - | Data collection instrument |
| EDD | - | Expected date of delivery |
| F | - | Female |
| fFN | - | Fetal fibronectin |
| gms | - | Grams |
| Hb | - | Haemoglobin |
| HPA | - | Hypothalamo pituitary axis |
| HUMA | - | Home uterine activity monitoring |
| HW | - | Housewife |
| ID | - | Identification |
| IUD | - | Intra uterine death |
| IUGR | - | Intra uterine growth restriction |
| Kg | - | Kilogram |
| LMP | - | Last menstrual period |
| LSCS | - | Lower segment caesarean section |
| M | - | Male |
| mg | - | Milligram |
| Min | - | Minute |

| | | |
|---|---|---|
| mL | - | Milli Liter |
| mm of Hg | - | Millimeter of mercury |
| MTP | - | Medical termination of pregnancy |
| n | - | Number of patients |
| OR | - | Odds ratio |
| P | - | Placebo |
| pH | - | Power of hydrogen |
| PIH | - | Pregnancy induced hypertension |
| PLB | - | Preterm labour birth |
| PNMR | - | Perinatal mortality rate |
| POG | - | Period of gestation |
| PPH | - | Post partum hemorrhage |
| PPROM | - | Preterm premature rupture of membranes |
| PR | - | Pulse rate |
| PTL | - | Preterm labour |
| SD | - | Standard deviation |
| STD | - | Sexually transmitted diseases |
| TV | - | Trichomonas vaginalis |
| USG | - | Ultrasound |
| Vs | - | Versus |

# ABSTRACT

**Introduction:** Inspite of considerable advances, preterm labour (PTL) continues to be a major cause of perinatal and neonatal morbidity and mortality. Infection is responsible for 40 to 60%. Earlier the infection earlier the PTL. The present study is an attempt to prevent preterm labor with clindamycin in pregnant women with infection as evident by increased pH (≥ 5)

**Objective:** Efficacy of Oral Clindamycin in prevention of PTL in pregnant women with vaginal pH ≥ 5

**Study design:** A randomized double blind placebo controlled trial.

**Study place:** Teaching hospital attached to Jawaharlal Nehru Medical College, Belgaum

**Source of data:** All the pregnant women meeting the selection criteria between 13 to 16 ± 1 weeks of gestation with vaginal pH≥5.

**Study interventions:** After screening pregnant women with infection (pH ≥ 5) were randomized to either Oral Clindamycin (300 mg of Clindamycin) twice daily for five days) or Placebo capsules. These women were followed up for the pregnancy outcome.

**Analysis:** $\chi 2$ test

**Results:** Of the 836 screened 520 were consented to participate in the trial of which 210 had vaginal pH of ≥ 5. These 210 women were randomly assigned to either clindamycin (110) or placebo group (100). The outcome was available for 198 women three women were excluded (twins). Pregnancy outcome of 195

women (100 in clindamycin and 95 in Placebo arm). The incidence of spontaneous PTL was significantly less in Clindamycin group (5% Vs 13.68%; p= 0.029). Similarly, the numbers of low birth weight babies were fewer in clindamycin group this was statistically significant (p-0.043). The late miscarriages in the present study were less in the clindamycin group however; this was statistically not significant (p-0.66).

**Conclusion:** Oral Clindamycin significantly reduced the incidence of spontaneous PTL and low birth weight without any side effects.

**Keywords**

Oral clindamycin; Bacterial vaginosis; Preterm labour; Vaginal pH;

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# INTRODUCTION

Preterm labor is defined as the presence of uterine contractions of sufficient frequency and intensity to effect progressive effacement and dilatation of the cervix prior to term gestation (between 20 and 37 weeks).[1,2]

Preterm labor precedes almost half of preterm births and preterm birth occurs in approximately 12% of pregnancies and is the leading cause of neonatal mortality in the United States.[1,2] In addition, preterm birth accounts for 70% of neonatal morbidity, mortality, and health care dollars spent on the neonate, largely due to the 2% of American women delivering very premature infants (< 32 week).[1,2]

In India, preterm labour precedes 30% preterm births.[3] Nearly 50-60% preterm births occur following spontaneous labor, 30% due to preterm premature rupture of membranes and rest are itrogenic terminations for fetal and maternal benefit.[3]

The overall incidence of preterm labour is around six to fifteen percent.[4] Incidence of preterm labour in current set up between the period of 2006-2007 was 10.2%. The PTL is the cause of 75% of all perinatal and 85% of all neonatal deaths and one half of all congenital neurological disability, including cerebral palasy.[5] Half of all the neonatal morbidity occurs in preterm births. The incidence of PNMR in India varies from 40 to 150 per 1000 births in contrast to 10 – 20 in developed countries.[6]

Unfortunately there is very little change or no change in the incidence of preterm labour in the last half century. Effective strategy for both prevention and management can definitely improve the pregnancy outcome.

Successful reduction of perinatal morbidity and mortality associated with prematurity may require the implementation of effective risk identification and behavioral modification programs for the prevention of preterm labor; these in turn require both an improved understanding of the psychosocial risk factors, etiology, and mechanisms of preterm labor and programs for accurate identification of pregnant women at risk for premature labor and delivery. In fact, recent evidence suggests that early identification of at-risk gravidas with timely referral for subspecialized obstetrical care may help identify women at risk for preterm labor and delivery and decrease the extreme prematurity (< 32 wk) rate, thereby reducing the morbidity, mortality, and expense associated with prematurity.[5]

Infection is responsible in 40 to 60% of cases of preterm labour.[3] Attempts have been made to screen for infections in the vagina, so that antibiotic treatment can be instituted to prevent preterm labour. Screening for abnormal vaginal flora, fibronectin, gram stain with neutrophils, vaginal pH are being attempted with varied rate of prediction.[4] Infections increase the pH of the vagina (except candidiasis). Out of all predictors of infection, increased vaginal pH (≥ 5) is simple and effective tool to detect vaginal infection.[5]

Several antibiotic classes and routes were used, including oral erythromycin, metronidazole, cephalosporins, vaginal clindamycin in second

trimester to prevent preterm labour but these did not demonstrate a statistically significant benefit.[7] Short courses of oral metronidazole administered late in the second trimester did not reduce the frequency of preterm delivery.[8]

The results of oral clindymycin have mixed opinions. A study on second trimester oral clindamycin was significantly associated with a lower rate of preterm labour.[4] However in some studies it has not shown significant benefit over placebo on the rate of preterm labour.[4]

Hence the present study was conducted to find out the effectiveness of oral clindamycin in prevention of spontaneous preterm labour, miscarriages and of low birth weight in pregnant women with vaginal pH $\geq$ 5.

# OBJECTIVES

The objectives of the present study were;

**Primary**

To find out the effectiveness of oral clindamycin in prevention of spontaneous preterm labour in pregnant women with vaginal pH ≥ 5.

**Secondary**

To find out the effectiveness of oral clindamycin in prevention of low birth weight and late miscarriages in pregnant women with vaginal pH ≥ 5.

# REVIEW OF LITERATURE

## Preterm labour

Inspite of considerable advances in obstetrical care preterm labour continues to be a major cause of perinatal and neonatal morbidity and mortality.

Preterm labor refers to the onset of uterine contractions of sufficient strength and frequency to effect progressive dilatation and effacement of cervix between 20 and 37 weeks of gestation.[4]

Preterm labour is defined as the occurrence of regular uterine contractions (four or more in 20 minutes or eight or more in one hour) and cervical changes (effacement equal to or greater than 80% and dilatation equal to or greater than 1 cm) in women with intact fetal membranes and gestational age 37-20 weeks.[9]

Preterm labor complicates 5-10% of pregnancies and is a leading cause of neonatal morbidity and mortality worldwide. Of all early neonatal deaths, not related to congenital malformations, 28% are due to preterm birth.[10] Preterm birth rates range from 5% to 7% of live births in some developed countries, but are estimated to be substantially higher in developing countries.[11]

Unfortunately, the incidence of preterm labor has changed very little over the last 40 years. It has been widely recognized that its prevention and/or effective management will improve neonatal outcome and will have a profound impact on society and long-term public healthcare costs.

## Epidemiology

### Incidence

Overall incidence of preterm labor is 6 to 15%[12] one out of which 50% to 60% are spontaneous, 25% preterm pre-labor rupture of membranes (PPROM), 25% Iatrogenic preterm (obstetric intervention to avoid maternal or fetal compromise).[4]

In the United States, preterm delivery affects one in 10 births responsible for 75% of neonatal deaths, even greater births in developing countries, excluding those related to congenital malformations.[13]

In India preterm labor is 23.3% and preterm delivery is 10 to 69%.[14] A study done in Lucknow reported an incidence of 20.9% preterm birth.[14]

Incidence of preterm labour in current set up between the period of 2006-2007 was reported as 10.2%.

A study[15] stated that, incidence of first time hospitalization for preterm labor is 9% with 38% delivering in their first episode. According to annual vital statistics in USA percentage of infants delivering before 37 weeks is continuously rising from 11% in 1998 to 12.3% in 2003.[16]

Due to continued innovation in neonatal intensive care facilities and obstetric interventions, fetal survival is now possible even at 20 weeks gestation in developed countries. However, in even the best setups in developing countries, salvage is rare below 28 weeks of gestation.

**Etiology**

A previous history of preterm labor is the strongest risk marker. It has been estimated that the incidence of preterm labor in subsequent pregnancies after one preterm birth rises to 14.3% and after two preterm births to 28%,[16] multiple pregnancy, cigarette smoking, cervical incompetence, uterine anomalies, uterine over-distension (polyhydraminos, macrosomia, fibroids), previous cervical surgery, using smokeless tobacco,[17] bleeding in early pregnancy[18] bacterial vaginosis, poor socioeconomic or educational status, and young or advanced maternal age. Pre-conceptional multivitamin treatment was inversely associated with both early and late preterm birth.[19] Short interval between pregnancies (less than 12 months) domestic violence, especially injury due to physical abuse.

Unfortunately, most of these risk markers are poor predictors of preterm labor as they have variable sensitivities (35-60%) and positive predictive values (15-30%).[20] Out of all these 40 to 60% is due to infection.

Infection

Infection is closely associated with PPROM, which accounts for almost one third (40-60%) of preterm labor. Abnormal genital tract flora at early second trimester was associated with preterm birth with an odds ratio (OR) of 1.4 to 2.[21,22]

Bacterial vaginosis (BV) is defined as an imbalance in the normal vaginal flora with diminution in the normally-predominant lactobacilli and the

proliferation of other anaerobic bacteria.[23-26] Lactobacilli are the major elements needed to maintain a healthy genital status by production of lactic acid, hydrogen peroxide, bacteriocins, block of attachment to the vaginal epithelium and growth inhibition of pathogenic microorganisms.[27]

Bacterial vaginosis may be present in up to 10 to 25% of pregnant women[28] and up to 64% of women attending sexually transmitted diseases (STD) clinic. Half of these women with BV are asymptomatic. An association has been found between BV and preterm labor and it has been found to increase the risk of preterm labor by two-fold.[29]

Asymtomatic bacterial vaginosis and trichomonas vaginalis confer a modest risk of spontaneous preterm birth[27] the most accepted mechanism of infection causing preterm birth is ascending infection. According to this there is a break in the normal physiological barrier that separates the products of conception from the vaginal flora. The vaginal bacteria ascend and colonize the deciduas and the chorion, eventually proliferating and invading the amniotic fluid and the featus. Under normal circumstances the membranes are separated from vaginal flora by the cervix and endocervical mucus. Changes in the antibacterial properties of cervical mucus play an important role in facilitating ascending infection.[30]

Bacterial vaginosis is characterized by an overgrowth of *Gardnerella vaginalis*,[31] anaerobes and *Mycoplasma hominis*[32] in the absence of lactobacilli and is clinically diagnosed by the presence of three of four Amsel criteria: (a) presence of thin, grayish homogenous discharge, (b) vaginal pH greater than 4.5,

(c) presence of clue cells and (d) positive whiff test (fishy odor on addition of potassium hydroxide).[33]

A study,[22] concluded that, infection is reponsible in 40% of cases and earlier the abnormal genital tract colonization is detected the greater is the risk of adverse outcome. Another study[4] from Lucknow reported that, genitourinary infection was the second commonest cause (20.7%). Asymptomatic bacteriurea, gonococcal cervicitis and bacterial vaginosis are strongly associated with preterm labor and the role of chlamydia, candida, trichomonas and urea plasma is less clear.[34]

Decreased numbers of lactobacillus are linked to preterm birth in cohort studies.[35] A study[36] reported that the risk for spontaneous preterm birth among women with BV was doubled. The samples were obtained early in pregnancy. Another study[37] also reported that in low-risk patients, BV was not a strong risk factor for preterm birth. A metaanalysis[30] concluded that, BV increased the risk of PLB more than two folds. Authors in a study[38] state that increase in E coli (commonest) and Klebsiella pneumoniae in vagina are independent risk factors for preterm birth.

During prenatal care, standard practices should be applied for screening for bacterial vaginosis gonorrhea and chlamydia infection in patients for prevention of preterm labor. Attempts have been made to screen for bacterial infections in the vagina so that antibiotic treatment can be instituted to prevent PPROM and hence, preterm labor. Such an approach would potentially reduce the incidence of preterm births by about 25%.[29]

**Prediction of preterm labor**

Up to 75% of preterm labor occurs either spontaneously or following PPROM and many attempts have been made to predict the onset of preterm labor so that measures could be taken to prevent its occurrence.[4]

- Home uterine activity monitoring (HUAM)
- Salivary estriol
- Screening for BV
- Screening for fetal fibronectin (fFN)
- Cervical ultrasonography (cervical length assessment)

*Home uterine activity monitoring*

Home uterine activity monitoring is based on the principle of tocodynamometry, tried in women with risk markers for preterm labor. The technique involves telemetric recording of uterine contractions and transmission of the same to a monitoring center and daily feed back from the healthcare practitioner to offer patient support and advice. However it is not found useful in reducing the incidence of preterm labour. Recently, a large randomized trial involving 2422 patients showed no benefit of HUAM in predicting preterm labor.[39] Hence, it cannot be recommended in routine clinical practice.

*Salivary estriol*

Premature activation of hypothalamic pituitary axis (HPA) in preterm labor may increase the serum and salivary levels of estriol in the mother and this may predict the onset of preterm labor early. Two prospective trials showed that

salivary estriol was more effective in predicting preterm labor.[40] However, this test has very poor sensitivity and specificity and has a very high false positive rate.

*Screening for fetal fibronectin*

Fetal fibronectin is a basement membrane protein produced by the fetal membranes and functions as an 'adhesion binder', is normally detectable in cervical secretions until 16-20 weeks of gestation.

Appearance of fFN in cervical secretions after 24 weeks of gestation heralds the onset of preterm labor. A meta-analysis of 40 studies revealed a very high negative predictive value for fFN in predicting the onset of preterm birth in the next three weeks.[41]

The specificity of fFN test for predicting preterm delivery within 1 week and 3 weeks was 71% and 59%, respectively.[41] It appears that a negative fFN test is useful in ruling out an imminent preterm delivery, whereas the implication of a positive test is uncertain. Its costly, usually takes 24 hours for reporting.

*Cervical ultrasonography (cervical length assessment)*

Indicators of cervical incompetency or onset of labor is shortening of the cervix. Assessment of cervical length using ultrasound as a predictor of preterm labor arose after authors[42] established the normal distribution of cervical lengths after 22 weeks of gestation. A prospective trial,[42] 2915 women evaluated by serial cervical ultrasonography reported a relative risk of preterm delivery of

9.57, 13.88 and 24.94 for cervical lengths of < 26 mm, < 22 mm and < 13 mm, respectively at 28 weeks of gestation.

There is also a wide variation in predictive values. A systemic review[43] of 35 studies involving cervical length assessment revealed a very wide variation in sensitivity (68-100%) and specificity (44-79%). Hence, currently there is no strong evidence to support routine cervical assessment using ultrasound between 24-28 weeks for the purpose of predicting preterm delivery.

*Screening for bacterial vaginosis*

Gram stain score

Gram stain score of 9 to 10 had significantly increased preterm births at <37, <35, and 32 weeks gestation and/or a birth weight less than 2500 g or less than 1500 g.

A multricentric study undertaken to identify early pregnancy vaginal markers predictive of subsequent preterm birth concluded that, women with a vaginal pH of 5.0 or greater or a vaginal pH of 4.5 or greater and a Gram stain score of 9 to 10 had significantly increased preterm births at <37, <35, and 32 weeks' gestation and/or a birth weight less than 2500 g or less than 1500 g.[5]

Neutrophils

Vaginal neutrophils > 5 per oil field were more likely to deliver newborn infants weighing less than 2500 gms in (14:806 versus 10.700 $p<0.001$) and less than 1500 gms in (4.6% versus 3.3% $p<0.01$).[44]

Vaginal pH

Vaginal pH is a quick, inexpensive, 'bed-side' diagnostic test. As pH correlates inversely with the functional amount of lactobacilli in the vagina.[45]

In prospective study,[46] normal pregnancy vaginal pH (using a pH meter with connected glass electrode) was found to be between 3.8 and 4.0 (1 SD +/- 0.3) at the introitus, mid-vaginal, and at the anterior and posterior fornix. Elevated pH values are due to disturbed vaginal flora. Study recommended vaginal pH measurement for an quick detection of infection.

Vaginal pH can be determined with litmus paper. A pH greater than 4.5 is often found in patients with *Trichomonas* infection or bacterial vaginosis (84-97% sensitive, 57-78% specific). Recent intercourse, douching, cervical mucus, and blood can lead to false-positive results.

- Bacterial vaginosis: pH is 5.0-6.0.
- Vaginal candidiasis: pH is less than 4.5.
- *Trichomonas vaginalis* (TV) infection: pH is 5.0-7.0.

A study concluded that, women with increased vaginal pH had increased pretermbirth and low birthweight rates.[5]

Another study[47] showed that the sensitivity of high vaginal pH in identifying women with BV or TV is 84.4% and pH >5 associates with an adverse pregnancy outcome. A study[5] also obtained the same results.

Elevated vaginal pH values such as a pH of more than 4.6 introitus or more than 4.9 posterior fornix are due to disturbed vaginal flora and lead to the possibility of preterm labor and prematurity. According to a study,[46] vaginal pH >5 was associated with preterm labour birth (PLB) and PPROM ($p< 0.05$).

Attempts have been made to screen for infections in the vagina, so that antibiotic treatment can be instituted to prevent preterm labour. Screening for abnormal vaginal flora, fibronectin, Gram's Stain with neutrophils, vaginal pH, are being attempted with varied rate of prediction.[4] Infections increase the pH of the vagina (except candidiasis). Out of all predictors of infection, increased vaginal pH (≥5) is simple and effective tool to detect vaginal infection.[5]

Several antibiotic classes and routes were used, including oral Erythromycin, Metronidazole, Cephalosporins, Vaginal Clindamycin in second trimester to prevent PTL, Metronidazole: Short courses of oral Metronidazole administered late in the second trimester did not reduce the frequency of preterm delivery.[8] Metronidazole does not reduce early preterm birth in high risk pregnant women selected by history and a positive vaginal fFN test. Preterm delivery may be increased by metronidazole therapy. Second trimester metranidazole used alone is linked with a greater risk of preterm delivery in a high risk population. Use of metranidazole a common treatment for bacterial vaginosis and Trichomonas vaginalis, should be avoided during the second trimester of pregnancy in this population.[8]

Erythromycin

Compared with placebo, use of macrolides in mid-trimester was associated with a significantly lower rate of preterm births (odds ratio [OR] 0.72; 95% confidence intervals [CI] 0.56–0.93, p=0.01). The studies included women given oral and intravaginal antibiotic therapy. The sole trial employing intravaginal erythromycin showed significant improvement (OR 0.47; 95% CI 0.23–0.95, p=0.04)[48] whereas the combination of two trials with oral treatment did not demonstrate a statistically significant benefit (OR 0.77; 95% CI 0.59–1.01, p=0.06).[5,49]

## CLINDAMYCIN

### Pharmacology[50]

Clindamycin is a semi synthetic antibiotic produced by a 7(s) chloro– substitution of the (7) R hydro group of the parent compound lincomycin. It was isolated from the soil fungus *Streptomyces lincolnensis*, and first synthesised in 1967. Each capsule contains 150 mg, 300 mg of clindamycin hydrochloride. The pharmacological forms available are capsules, injectables. Orally 600 – 1800 mg/day divided in two, three, four equal doses and taken with full glass of water to avoid esophageal irritation. The drug is rapidly absorbed with average peak of 2.50 microgms /ml in 45 min, l.5l microgms/ml in 3 hours and 0.70 microgms/ml in six hours. It is widely distributed in body fluids and tissues including bones. Drug is metabolised by the liver and its average biological half life is two to four hours. Mode of action is bacteriostatic effect on Gram-positive aerobes and a

wide range of anaerobic bacteria, acts by inhibiting protein synthesis. Clindamycin is identified as pregnancy category B drug by FDA.

It is 10% excreted in urine three to six percent in fecal and remainder as bioactive metabolites. Few side effects of this drug are nausea, vomiting, abdominal pain, diarrhea, maculopapular rash, urticaria, esophagitis hypersensitivity reactions, blood dyscrasias, and disturbances of hepatic function.etc. Contraindicated in patients with pseudomembraneous colitis and meningitis. Should not be given along erythromycin and neuromuscular blockers. Should be used only if clearly needed in lactation. used to treat staphylococcal osteomyelitis, anaerobic sepsis associated with necrotising enterocolitis, protozoal infection, malaria, toxoplasmosis, overt bacterial vaginosis and some also advocate screening for asymptomatic vaginosis in early pregnancy if vaginal pH exceeds 4.5.[50]

There is no evidence of teratogenicity, and safe during lactation. There is just one accidental report of a baby who passed two bloody stools while being breast fed by such a mother.[50]

Vaginal clindamycin cream

A 2% clindamycin vaginal cream, when compared with placebo administered to women with abnormal genital tract flora before 20 weeks' gestation, can reduce the incidence of preterm birth by 60% and hence the need for neonatal intensive care.[51]

Clindamycin 5 gms of the 2% vaginal cream once a day for 7 days reduced the risk of very preterm birth in two recent trials when given to women with a clearly abnormal vaginal flora or frank bacterial vaginosis in early pregnancy (<16 weeks).[50]

Oral clyndamycin

Treatment of asymptomatic abnormal vaginal flora and bacterial vaginosis with oral clindamycin early in second trimester significantly reduces the rate of late miscarriage and spontaneous preterm birth in a general obstetric population.[3] Although oral clindamycin reduced late miscarriage and preterm birth in women with abnormal vaginal flora, this effect is unlikely to be mediated through a reduction in the incidence of histologic chorioamnionitis.[52]

A recent randomised controlled trial[8] concluded that treatment of asymptomatic abnormal vaginal flora and BV with oral clindamycin in early second trimester significantly reduces the rate of late misarriage and spontaneous preterm birth.

Clindamycin 300 mg twice daily by mouth for 5 days, reduced the risk of very preterm birth in two recent trials when given to women with a clearly abnormal vaginal flora or frank bacterial vaginosis in early pregnancy (<16 weeks).[50]

Clindamycin therapy was associated with significantly prolonged gestation and reduced cost of neonatal care in women with BV. Early screening

and treatment of BV with clindamycin saved approximately 24 euro per women.[53]

Because of the potential benefits to childbearing women, particularly those in developing countries, further research to determine its effects with greater certainty should be expedited. Hence is the need for the study.

# METHODOLOGY

The present study was conducted in the Department of Obstetrics and Gynaecology, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum.

**Study design**

A randomized double blind placebo controlled trial.

**Study period**

One year from January 2010 to December 2010.

**Study place**

Department of Obstetrics and Gynaecology, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum attached to Jawaharlal Nehru Medical College, Belgaum.

**Source of data**

All the pregnant women between 13 to 16 ± 1 week gestational period attending out patient Obstetrics and Gynaecology Department of KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum.

**Sample size**

A total of 264 pregnant women divided into two groups (Study group 132 women and placebo group 132 women).

**Sampling procedure**

Sample size was calculated using the formulae as below

$n = (z+z)^2\ 2p(1-p)/d^2$

with $\alpha = 5\%$;

$\beta = 20\%$

When P1 = 13/244 (5.34%)

P2 = 38/241 (15.77%)

$n = 132$

Hence a total of 264 women were considered for the study.

Assuming a total sample size of 264 subjects, 132 of whom are randomly assigned to receive clindamycin and 132 of whom are assigned to placebo (standard care), and assuming that 10% of those with standard care will experience preterm labour and 5% of those receiving clindamycin will experience preterm labour will then have 96% power to detect a 50% reduction in the occurrence of this outcome in the experimental group. Women without study drug are therefore two times as likely to preterm labour experience as those women treated with clindamycin.

**Randomization procedures:**

Subjects were randomly assigned to receive study medication or identically appearing placebo employing balanced randomization procedures. To ensure balanced randomization and to conceal the treatment assignment, a computer generated randomization list (a sequence of letters P (for placebo) and

C (for clindamycin)), with a random block size was utilized. The randomization list was stratified by clinical pharmacist. Using the above procedure, the required number of envelopes containing the study drug or placebo were prepared. The clinical pharmacist retained the randomization list. The envelopes containing the study medication or placebo were in the custody of the clinical pharmacist who in turn distributed them to the investigators. The randomization code was broken by the clinical pharmacist, when such need was dictated, but such need never arised.

**Selection Criteria**

Inclusion

1. Pregnant woman 13 to 16 ±1 weeks.
2. Singleton pregnancy.
3. Vaginal pH ≥ 5

*Exclusion Criteria:*

- Not willing to provide informed consent.
- History of antibiotic use within the previous 14 days.
- Current placement of a cervical cerclage.
- Current receipt of tocolytic therapy.
- History of cone biopsy.
- Uterine, cervical anomaly.
- Life threatening known fetal anomaly.
- Significant known medical complications like
    - Diabetes

- Renal diseases
- Collagen diseases
- Epilepsy
- Lupus
- Antiphospholipid syndrome
- Essential hypertension

**Method of Collection of Data**

Ethical clearance

The ethical clearance was obtained from Review Board of Jawaharlal Nehru Medical College, Belgaum. (Letter No. MDC/DOME/ dated 14.10.2009)

Screening and Enrolment

All potentially eligible women between the gestational period 13 to 16±1 week visiting for early antenatal visit were screened for eligibility based on selection criteria. Informed consent was obtained at the time of enrolment into the study from the eligible women. The informed consent form was provided by the investigator to the patient to be enrolled. The investigator obtained a signature or left hand thumb impression from the consented subject. The informed consent document was only a small component of the informed consent process. Adequate time was provided for describing the study and fielding questions from the patient and/or immediate family members. Fair balance was maintained while describing the risks and benefits of participation in the study. No undue pressure was placed on the patient to enroll in the trial.

**Photograph 1: Consent for participation in the study**

It was further explained that lack of participation will not affect the usual and anticipated standard of care. The women were enrolled in the study only after taking their signature or left hand thumb impression on informed consent form (Annexure I).

A unique subject ID was assigned to those women who consented for the study staring from 001. The following scheme was used for this purpose:

Data collection form

Data collection instrument containing information about present and past pregnancies was completed. Randomization to study drug or placebo was done after diagnosing vaginal pH. The investigator, previously trained in the administration of the questionnaire, completed the Antenatal Record of the data collection instrument at the time of enrolment into the study and the Delivery Record after delivery.

*Description of questionnaires*

Printed in English, the DCIs will comprise five parts. The first part, the contains general information and includes information on socio-demographic factors. The second part contain questionnaire (screening) for inclusion in the study. The third part contains final result of eligibility (after screening) information. The fourth part, contains age, occupation, education, current obstetric history ,previous history of preterm births, past obstetric history, labour and delivery record, general physical examination, systemic examination, fundal height, hemoglobin, intervention details were assessed by the investigator, as is

usual practice. The fifth part contained, standardized delivery details, date of delivery, period of gestation at delivery ,weight and sex of neonate.

| Part I | Part II | Part III | Part IV | Part V |
|---|---|---|---|---|
| • Name | • 13-16+1 Week POG | • Final result information | • Age at marriage | • Outcome data |
| • Address | • Singleton pregnancy | | • Family size | • Date of delivery |
| | • Antibiotic use | | • Parity | • Weight of baby |
| | • Fetal anomaly | | • Education | • Mode of delivery |
| | • Maternal medical complications | | • Economic indicators (e.g., ownership of home, land, cattle) | • Weeks at delivery |
| | • Cervical encerclage | | • Past pregnancy | • Gender |
| | • Fever | | • Current pregnancy | |
| | • Vaginal pH | | • Examination details | |
| | • Consent | | • Interventions | |

Study interventions

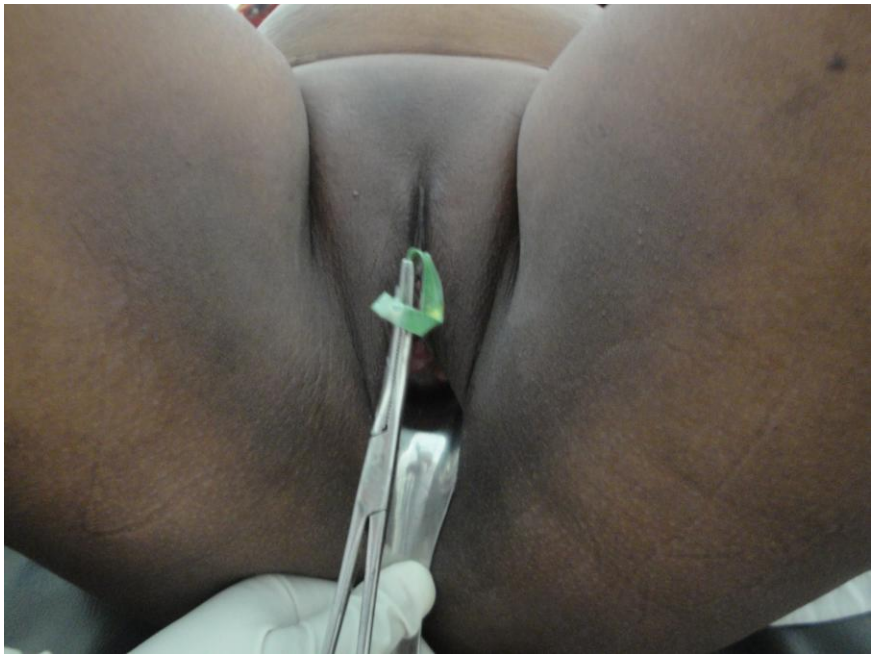
Every woman enrolled for the study received, either 10 tablets containing the active medication (300 mg of clindamycin) twice daily for five days or 10 identically appearing tablets of placebo, whose vaginal pH $\geq 5$.

Management and Administration of Intervention

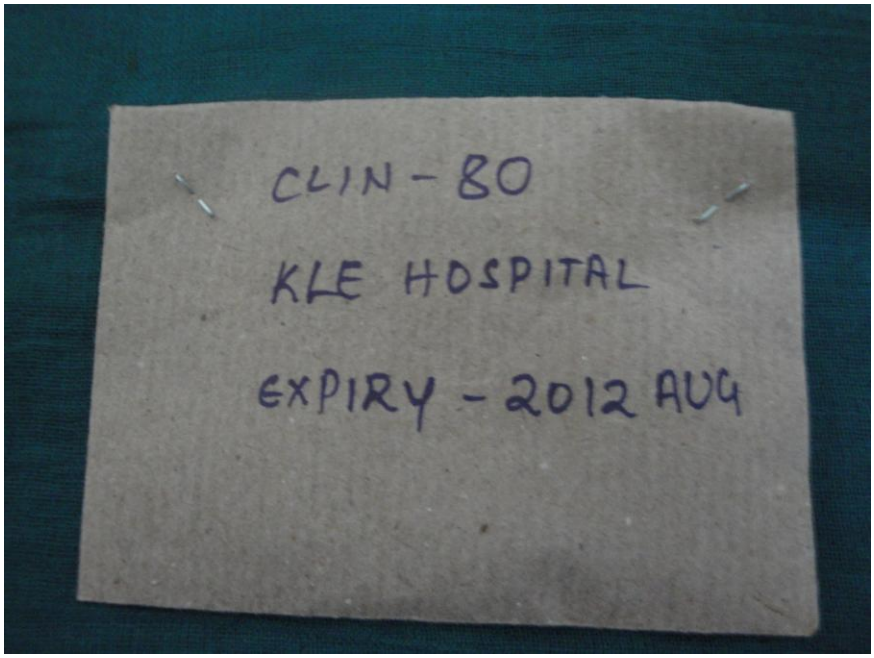
Eligible consented women underwent vaginal pH screening test, a litmus paper was seeped in the deep vagina (posterior fornix) and pH was assigned using a different colour code of pH. The women with pH ≥5 were randomized as per a double blinded randomization list prepared by clinical pharmacist and received either clindamycin (300mg) or placebo orally twice daily for five days. The clinical pharmacist used this randomized list to pack envelopes of five day courses of either clindamycin (300mg) or placebo to be taken twice daily. The clindamycin capsules were identical to and indistinguishable from placebo capsules and were masked to participants and investigators. Every envelop had a code on it (clin-001), expiry date of the drug and hospital name. The investigator allocated envelops consecutively to participants These women were followed up to look for their pregnancy outcome.

**Statistical Analysis**

The data was tabulated and master chart was prepared (Annexure IV) Analysis was done using percentages, rates and ratios. Chi square test was used to compare differences between the groups and analysed using Med Calc version 10.2.0.0. A probability value (‘p’ value) of less than or equal to 0.05 was considered as significant.



**Photograph 2. Vaginal pH screening test**




**Photograph 3. Pack envelopes of five day courses of either clindamycin (300mg) or placebo**

# RESULTS

In this study, a total of 836 cases were enrolled, out of which 520 had given consent for participating in the study. Based on the selection criteria 210 women were eligible to participate in this study. Out of which outcome data was available for 198. Out of these three were twins who were excluded hence a total of 195 were analyzed. Based on the computer generated randomization list these women were randomly allocated to receive either Clindamycin (n=100) and placebo (n=95).

**Flow chart of study population**

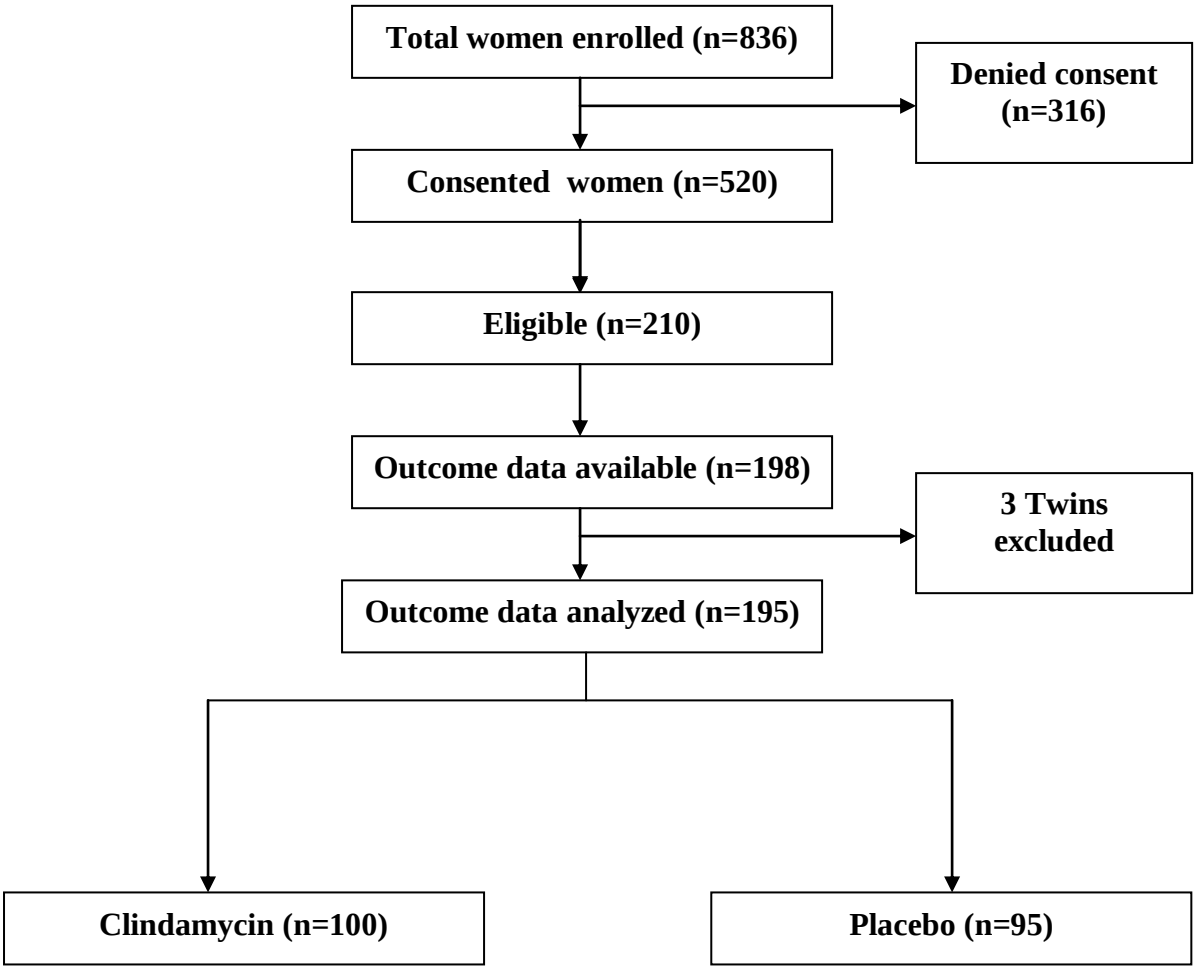


**Table 1. Baseline characteristics of the participants**

| Baseline characteristics | Clindamycin group (n=100) | Placebo group (n=95) | P value |
|---|---|---|---|
| Age [Years, mean (SD)] | 24.55(3.79) | 23.23(3.17) | 0.1341 |
| Occupation | | | |
| • House wife | 86/100(86%) | 80/95(84.21%) | 0.5899 |
| • Working | 10/100(10%) | 12/95(12.63%) | |
| • Laborer | 04/100(4%) | 02/95(2.11%) | |
| • professional | 00/100(0%) | 01/95(1.05%) | |
| Education | | | |
| • Illiterate | 02/100(02%) | 1/95(1.05%) | 0.3192 |
| • Read | 19/100(19%) | 12/95(12.63%) | |
| • Write | 29/100(29%) | 24/95(25.26%) | |
| • Primary | 33/100(33%) | 30/95(31.58%) | |
| • Secondary | 16/100(16%) | 22/95(23.16%) | |
| • Graduate | 01/100(1%) | 04/95(4.21%) | |
| • Post graduate | 00/100(00%) | 02/95(2.11%) | |
| Socio-economic status | | | |
| • White card | 15/100(15%) | 17/95(17.89%) | 0.5156 |
| • Green card | 18/100(18%) | 19/95(20.00%) | |
| • Yellow card | 61/100(61%) | 57/95(60.00%) | |
| • Pan card | 06/100(06%) | 02/95(2.11%) | |
| pH-value [mean(SD)] | 5.74(0.43) | 5.76(0.33) | |
| Parity [mean(SD)] | 0.53(0.69) | 0.55(0.68) | 0.9955 |
| Gestation at randomization [weeks, mean (SD)] | 14.51(1.86) | 14.68(1.26) | 0.8731 |
| Previous miscarriages | 10/100(10%) | 09/95(9.47%) | 0.8275 |
| Previous spontaneous preterm deliveries | 02/100(2%) | 04/95(4.21) | 0.699 |
| BMI [mean (SD)] | 20.14(3.59) | 19.94(4.67) | 0.6423 |
| Systolic blood pressure [mean (SD)] | 115.88(8.77) | 114.84(10.02) | |
| Diastolic blood pressure [mean (SD)] | 73.90(6.97) | 74.06(8.57) | |
| Hemoglobin [gm%, mean (SD)] | 10.77(1.26) | 11.77(1.19) | 0.1057 |

**Table 2. Vaginal discharge**

| Vaginal discharge | Clindamycin (n=100) | | Placebo (n=95) | |
|---|---|---|---|---|
| | **Number** | **Percent** | **Number** | **Percent** |
| Yes | 0 | 0.00 | 0 | 0.00 |
| No | 100 | 100.00 | 95 | 100.00 |
| **Total** | **100** | **100.00** | **95** | **100.00** |

p=1.000

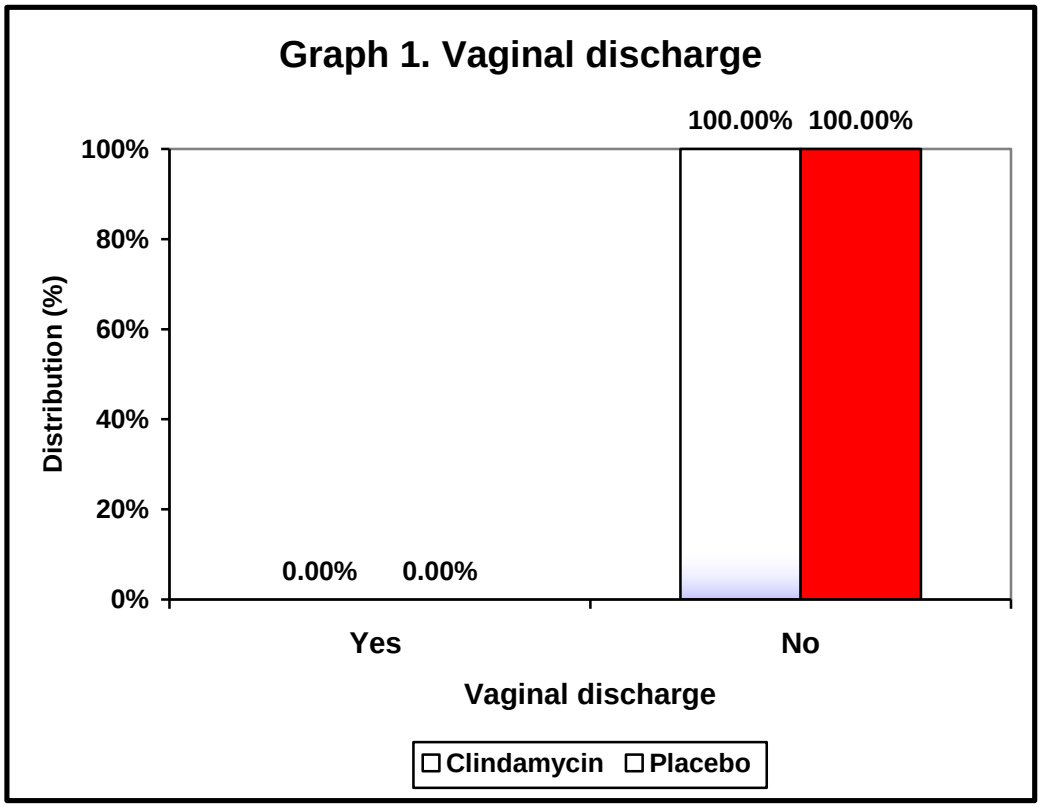


**Table 3. History of Puritis**

| Puritis | Clindamycin (n=100) | | Placebo (n=95) | |
|---|---|---|---|---|
| | **Number** | **Percent** | **Number** | **Percent** |
| Yes | 0 | 0.00 | 0 | 0.00 |
| No | 100 | 100.00 | 95 | 100.00 |
| **Total** | **100** | **100.00** | **95** | **100.00** |

p=1.000 (test of proportion)

Comparison of baseline maternal characteristics between the two groups. The groups were comparable for maternal demographic characteristics like (age, occupation, education, socioeconomic status), presence of vaginal discharge, history of purities, parity, previous obstetric outcome, previous history of preterm deliveries and estimated period of gestation ,body mass index, blood pressure and hemoglobin at the time of randomization. No statistically significant difference noted in both groups using chi square test and test of proportion.

**Table 4. Outcome data**

| **Clindamycin** | **100** |
|---|---|
| Term | 86 (86%) |
| Total Preterm | 13 (13%) |
| Spontaneous Preterm | 5 (5%) |
| *Induced preterm* | 8 (8%) |
| Abruption | 1 (1%) |
| IUD | 1 (1%) |
| Eclampcia | 1 (1%) |
| Oligohydroamnios | 1 (1%) |
| Preeclampsia | 2 (2%) |
| IUGR | 2 (2%) |
| **Placebo** | **95** |
| Term | 73 (76.84%) |
| Total preterm | 19 (20%) |
| Spontaneous preterm | 13 (13.68%) |
| *Induced preterm* | 6 (6.31%) |
| Anencephaly | 1 (1.05%) |
| Oligohydroamnious | 1 (1.05%) |
| Abruption | 2 (2.10%) |
| IUD | 1 (1.05%) |
| Preeclampsia | 1 (1.05%) |

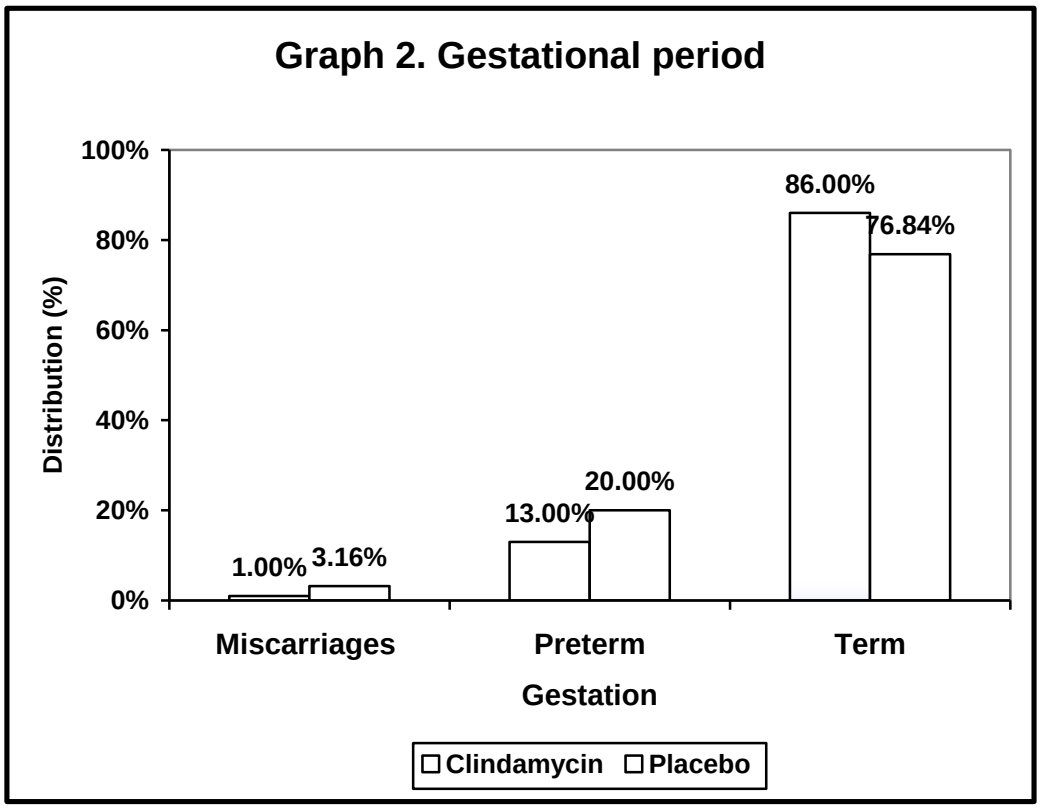
**Table 5. Mode of delivery**

| Outcome | Clindamycin (n=100) | | Placebo (n=95) | |
|---|---|---|---|---|
| | **Number** | **Percent** | **Number** | **Percent** |
| Normal delivery | 74 | 74.00 | 61 | 64.21 |
| Vaginal delivery | 7 | 7.00 | 13 | 13.68 |
| LSCS | 18 | 18.00 | 18 | 18.95 |
| Abortion | 1 | 1.00 | 3 | 3.16 |
| **Total** | **100** | **100.00** | **95** | **100.00** |

**Table 6. Gestational period**

| Gestation | Clindamycin (n=100) | | Placebo (n=95) | |
|---|---|---|---|---|
| | **Number** | **Percent** | **Number** | **Percent** |
| Miscarriages | 1 | 1 | 3 | 3.16 |
| Preterm | 13 | 13 | 19 | 20.00 |
| Term | 86 | 86 | 73 | 76.84 |
| **Total** | **100** | **100.00** | **95** | **100.00** |

p = 0.187




Total number of preterm births was less in clindamycin group compared to placebo group (13% vs 20%). However this difference was statistically not significant (p=0.187).

**Table 7. Spontaneous preterm deliveries**

| Deliveries | Clindamycin (n=100) | | Placebo (n=95) | |
|---|---|---|---|---|
| | **Number** | **Percent** | **Number** | **Percent** |
| PPROM | 5 | 5.00 | 9 | 9.47 |
| Established preterm | 0 | 0.00 | 4 | 4.21 |
| **Total** | **5** | **5.00** | **13** | **13.68** |

p = 0.0299

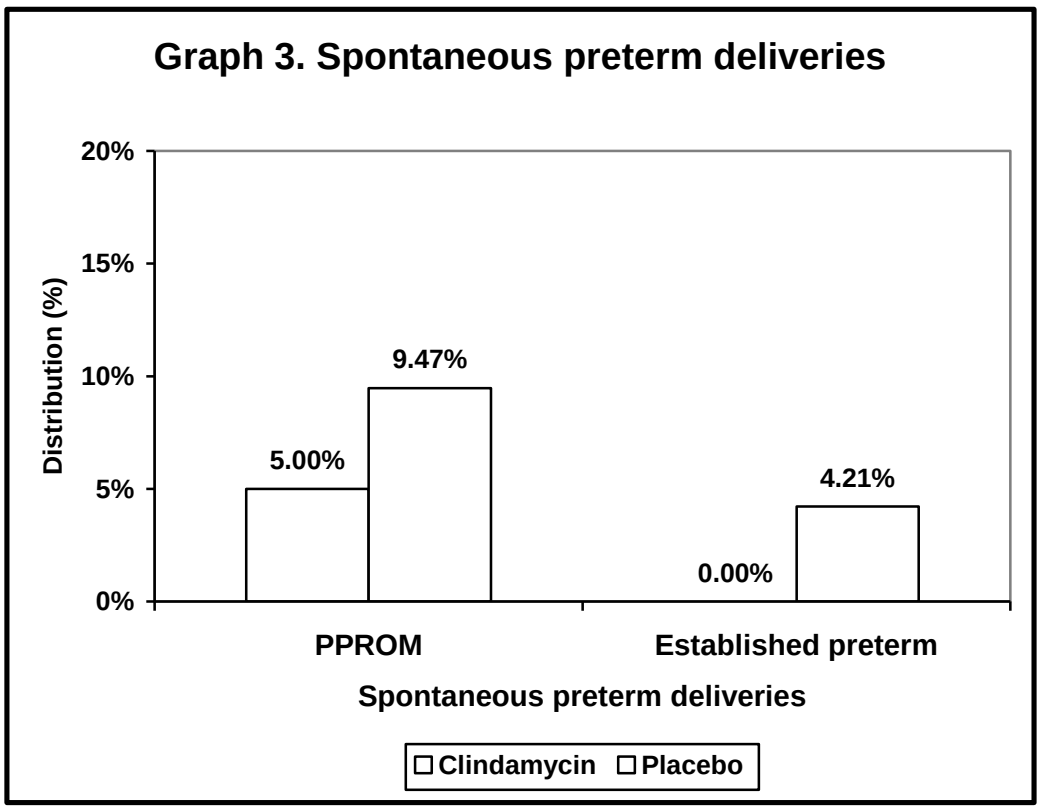
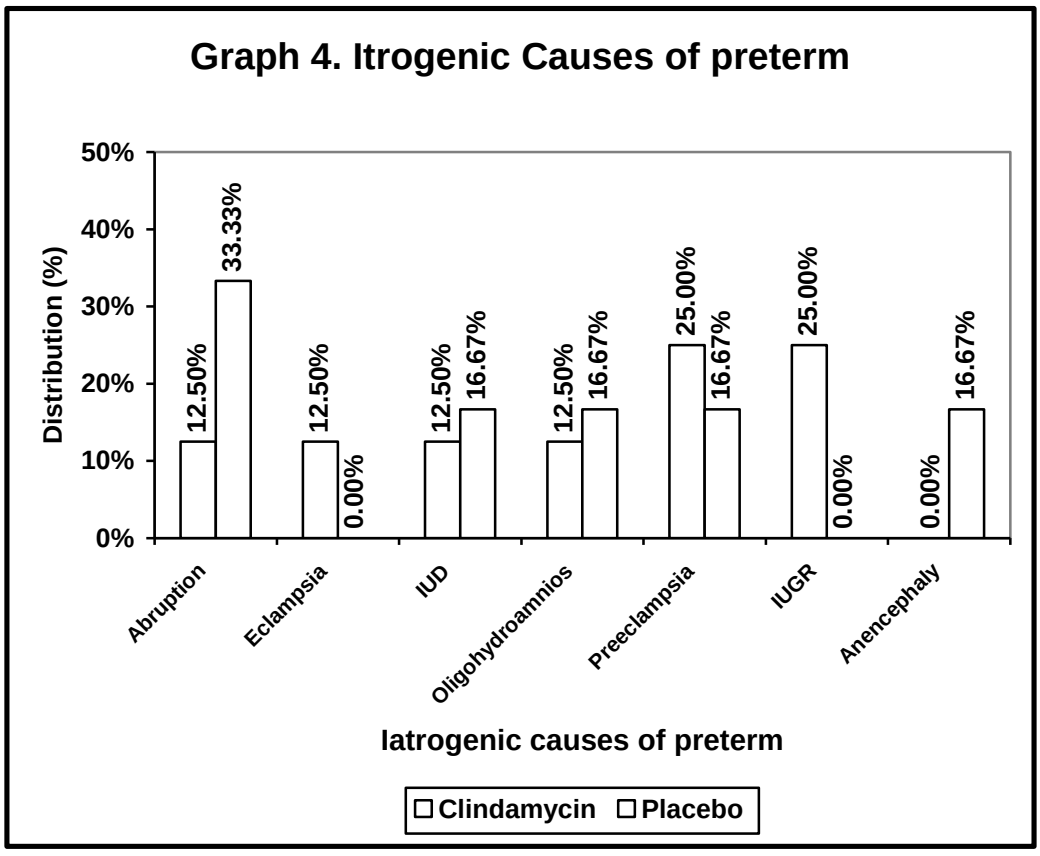


**Table 8. Itrogenic Causes of preterm**

| Causes | Clindamycin (n=8) | | Placebo (n=6) | |
|---|---|---|---|---|
| | **Number** | **Percent** | **Number** | **Percent** |
| Abruption | 1 | 12.50 | 2 | 33.33 |
| Eclampsia | 1 | 12.50 | 0 | 0.00 |
| IUD | 1 | 12.50 | 1 | 16.67 |
| Oligohydroamnious | 1 | 12.50 | 1 | 16.67 |
| Preeclampsia | 2 | 25.00 | 1 | 16.67 |
| IUGR | 2 | 25.00 | 0 | 0.00 |
| Anencephaly | 0 | 0.00 | 1 | 16.67 |
| **Total** | **8** | **100.00** | **6** | **100.00** |



In Clindamycin group out of 100 women, 86 (86%) had term delivery, 5 (5%) had spontaneous preterm births and remaining 8 (8%) were terminated for iatrogenic cause, being Preeclampsia in two each (25%) and one each (12.50%) in abruption, IUD, oligohydramnios, and eclampsia, two each in IUGR (25%). In placebo group out of 95 women, 73 (76.84%) had term delivery, 13 (20.00%) had spontaneous preterm births and remaining 6 (6.3%) were terminated for iatrogenic cause being abruption in two each (33.33%) and one each (16.67%) had oligohydramnios, IUD, preeclampsia and anencephaly. Spontaneous Preterm births were significantly (p-0.029) less in clindamycin group compared to placebo (5% Vs 13.68%)

In the proportions of late miscarriages clindamycin 1/100 [1%] *vs* placebo 3/95 [3.16%] significant percentage difference of 2.16% was noted. However p=0.665 Non significant.

**Table 9. Birth weight**

| Birth weight (gms) | Clindamycin (n=100) | | Placebo (n=95) | |
|---|---|---|---|---|
| | Number | Percent | Number | Percent |
| < 500 | 1 | 1.00 | 2 | 2.11 |
| 501 to 999 | 0 | 0.00 | 2 | 2.11 |
| 1000 to 1499 | 1 | 1.00 | 6 | 6.32 |
| 1500 to 1999 | 4 | 4.00 | 9 | 9.47 |
| 2000 to 2499 | 27 | 27.00 | 19 | 20.00 |
| 2500 to 2999 | 49 | 49.00 | 36 | 37.89 |
| 3000 to 3499 | 17 | 17.00 | 20 | 21.05 |
| > 3500 | 1 | 1.00 | 1 | 1.05 |
| **Total** | **100** | **100.00** | **95** | **100.00** |

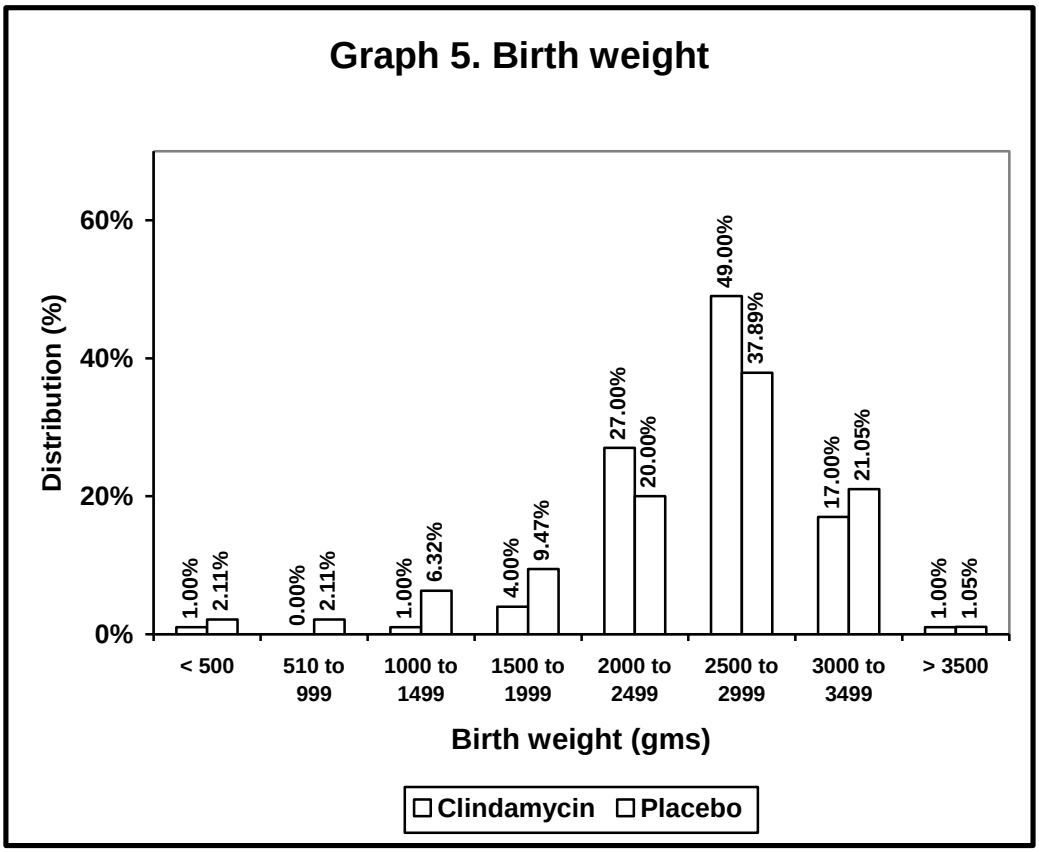
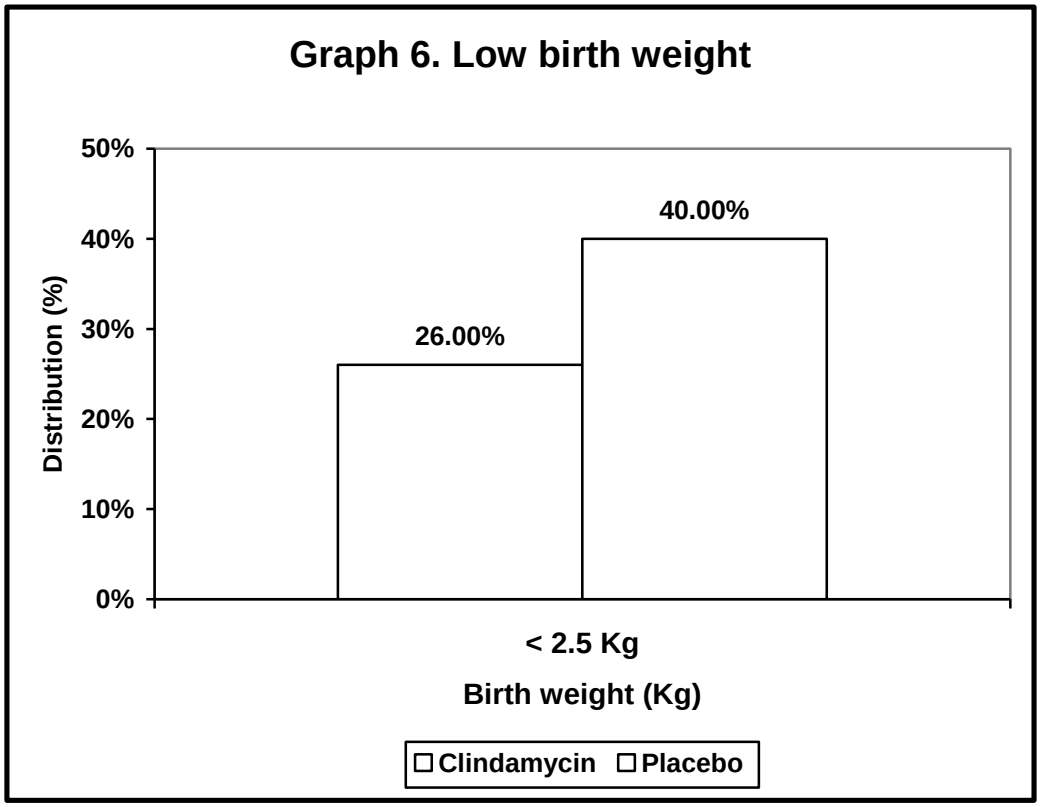


**Table 10. Low birth weight**

| Birth weight | Clindamycin (n=100) | | Placebo (n=95) | |
|---|---|---|---|---|
| | **Number** | **Percent** | **Number** | **Percent** |
| Babies with < 2.5 Kg | 26 | 26.00 | 38 | 40.00 |
| **Total** | **26** | **26.00** | **38** | **40.00** |

p = 0.0434




Women receiving clindamycin had significantly fewer low birth weight babies than did women who received placebo (26/100 [26%] *vs* 38/95[40%]); percentage difference of 14% (p value=0.0434)

Side effects included were any gastrointestinal upset, nausea, vomiting, diarrhea, abdominal pains, rashes, dermatitis, urticaria, throat irritation, headaches. In this study no side effects were reported.

# DISCUSSION

This prospective double blind, randomized, placebo controlled trial evaluated the efficacy of oral clindamycin in prevention of spontaneous preterm labor, low birth weight and late miscarriages in women with vaginal pH $\geq$5 in early pregnancy (12-17 weeks). Limited data available on the effect of antibiotics on spontaneous preterm labor, low birth weight, late miscarriages in women with abnormal vaginal flora.

Abnormal vaginal flora (genital tract infections) is associated with increased vaginal pH (except for candida infection).[44] The same was noted by Nugent Gram stain scoring in other study.[5] Pregnant women were screened for vaginal pH and women with pH of $\geq$ 5 were randomly assigned to either clindamycin or placebo. These women were followed to find out the pregnancy outcome. Oral Clindamycin 300 mg twice a day for five days, (the antibiotic with wider spectrum and effective against most of the organisms responsible for abnormal vaginal flora) was used in this trial. Mycoplasma species are the most frequently found in mid trimester amniotic fluid of women who subsequently delivered preterm. Clindamycin is the effective antibiotics for preventing preterm births.[3]

The use of clindamycin is associated with mixed outcome in earlier studies (One study had effect and other did not) on the effectiveness of clindamycin.[3,8]

Furthermore, results of longitudinal follow up studies have shown that spontaneous resolution of bacterial vaginosis later in pregnancy were not associated with a reduction in risk of preterm birth, suggesting that treatment at a late stage in pregnancy may not be beneficial.[54,55]

Of the 836 screened 520 were consented to participate in the trial of which 210 had vaginal pH of $\geq$ 5. These 210 women were randomly assigned to either clindamycin (110) or placebo group (100). The outcome was available for 198 women three women were excluded (twins).Pregnancy outcome of 195 women (100 in clindamycin and 95 in Placebo arm).

Spontaneous Preterm births were significantly (p-0.029) less in clindamycin group compared to placebo (5% Vs 13.68%) similar observation was noted by another study,[8] however contrary observation was made by other study.[3] The study which did not show effectiveness may be because of the antibiotics used in the trial.[3] Metrinidazole used alone in second trimester is linked with a greater risk of preterm delivery in a high risk population.[3]

Total number of preterm births was less in clindamycin group compared to placebo group (13% vs 20%). However this difference was statistically not significant (p=0.187).

There was no significant difference between the groups among induced preterm births due to the obstetric indications (Abruption, eclampsia, intrauterine death, oligohydroamnios, preeclampsia, Intrauterine growth restriction and anencephaly) (p-0.64).

Similarly, the numbers of low birth weight babies were fewer in clindamycin group this was statistically significant (p-0.043) however this was not significant in other study[8] (p-0.53).

The late miscarriages in the present study were less in the clindamycin group however; this was statistically not significant (p-0.66). Similar observations were noted in other study[8] also.

In the present study no pregnant woman reported any side effects of the drug (Clindamycin) contrary to the other study[8] where in following side effects were noted (gastrointestinal upset, nausea, vomiting, diarrhea, abdominal pain, rashes, vulgovaginal candidiasis, throat irritation and headache). This may be probably due to the belief of pregnant woman, that these side effects were pregnancy related and not drug induced.

The limitation of the present study was that, it was done in single ethnic group with 132 in each arm. Hence, the findings of the present study need to be confirmed with multicentre, ethnic groups with a larger sample size.

# CONCLUSION

It is evident from this study that oral Clindamycin reduces the occurrence of spontaneous preterm labor and low birth weight babies in women with (pH ≥5) increased vaginal pH (indicator of abnormal genital flora) compared to placebo. These findings need to be confirmed by larger sample size in multicentre and different ethnic population.

**Recommendations**

Increased vaginal pH (≥5) is an important tool to detect the abnormal genital flora in early pregnancy as this is increasingly associated with preterm labor. This group of women who have increased vaginal pH (5≥) can be treated with oral Clindamycin 300 mg BD for five days to decrease the occurrence of spontaneous preterm labor.

# SUMMARY

A randomized, double blind placebo controlled trial (computer generated, randomized number sequence, block size of 2) was performed on 210 consenting women fulfilling eligibility criteria (13-16$\pm$1 week period of gestation and singleton and vaginal pH $\geq$5) in antenatal clinic at KLES Dr. Prabhakar Kore Hospital and MRC, Belgaum.

Prediction of preterm labor was done using vaginal pH estimation.

In this study, of the 836 screened 520 were consented to participate in the trial of which 210 had vaginal pH of $\geq$ 5. These 210 women were randomly assigned to either oral clindamycin (110) or placebo group (100). The outcome was available for 198 women three women were excluded (twins).Pregnancy outcome of 195 women (100 in clindamycin and 95 in Placebo arm).

Clindamycin group had significantly fewer spontaneous preterm labor 5 [5%] vs 13 [13.68%] (p=0.0299) and low birth weight 26/100 [26%] *vs* 38/95 [40%] (p value=0.0434) compared to placebo group respectively.

In the proportions of late miscarriages clindamycin 1/100 [1%] *vs* placebo 3/95 [3.16%] significant percentage difference of 2.16% was noted. However p=0.665 Non significant.

In the present study no pregnant woman reported any side effects of the drug (Clindamycin like (gastrointestinal upset, nausea, vomiting, diarrhea, abdominal pain, rashes, vulgovaginal candidiasis, throat irritation and headache).

This may be probably due to the belief of pregnant woman, that these side effects were pregnancy related and not drug induced.

It is evident from this study that, increased vaginal pH (≥5) is an important tool to detect the abnormal genital flora in early pregnancy as this is increasingly associated with preterm labor and this group of women who have increased vaginal pH (5≥) can be treated with oral clindamycin 300 mg BD for 5 days to decrease the occurrence of spontaneous preterm labor.

Hence screening for asymptomatic abnormal vaginal flora and bacterial vaginosis which is responsible for spontaneous preterm births and treating with oral clindamycin 300 mg BD for 5 days is safe and effective option.

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# ETHICAL CLEARANCE

K.L.E.SOCIETY'S
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Ref. No. :MDC/DOME/

Date: 14/10/2009

To,

Dr. Pallavi Chalasani,
Postgraduate student in
Department of Obstetrics & Gynaecology,
J.N.Medical College,
Belgaum.

Dear Dr. Pallavi Chalasani,

The JNMC – Institutional Ethics Committee on Human Subjects Research met on 12th October, 2009 to consider your application for approval of the research project **"ORAL CLINDAMYCIN FOR PREVENTION OF PRETERM LABOR (ptl) IN PREGNANCIES OF 13 TO 16 +1 WEEKS WITH VAGINAL pH≥5 – A RANDOMIZED DOUBLE BLIND PLACEBO CONTROLLED TRIAL."**.

After review of the documents submitted by you and satisfactory explanations provided to the members, the committee has provided approval date through October 11th, 2010 at which time the study will be reviewed by the committee.

If you have any questions concerning the above, please feel free to contact the committee office.

Sincerely,

(Dr.V.D.Patil)
Chairman,
JNMC Institutional Ethics Committee on
Human Subjects Research

# ANNEXURE I – CONSENT FORM

## INFORMED CONSENT DOCUMENT

ID NO: | | | | | |

**Title: ORAL CLINDAMYCIN FOR PREVENTION OF PRETERM LABOR IN PREGNANCIES OF 13 TO 16±1 WEEKS WITH VAGINAL PH ≥ 5 – A RANDOMIZED DOUBLE BLIND PLACEBO CONTROLLED TRIAL.**

You are requested to participate in a study that is an attempt to find out the efficacy of oral clindamycin in prevention of preterm labor in women with higher vaginal pH i.e.≥5 (Indicator of abnormal vaginal flora) in early pregnancy. About 264 pregnant women with vaginal pH ≥ 5, attending the outpatient department of KLE'S Dr. Prabhakar Kore Hospital and Medical Research Centre, will be enrolled in the study. The overall incidence of preterm labor (PTL) is around 6-15%. Infection is responsible for almost 40-60% of Preterm labor. Majority of perinatal and neonatal deaths occur in preterm infants. Effective strategy for both prevention and management can definitely improve the perinatal outcome.

This study is done by Dr. Pallavi Chalasani postgraduate in Obstetrics and Gynecology under direct supervision and guidance of Dr. M. B. Bellad, Professor, Department of OBG, J. N. Medical College, and Belgaum.

You need to be eligible meeting the selection criteria to participate in this study. You should be willing to provide information about you and your previous pregnancy details.

If you agree to participate in this study, we would ask you to undergo a test for detecting vaginal pH to know the degree of infection, which would cause slight discomfort to woman. The women with pH $\geq$5 will be randomised to receive either clindamycin 300mg or placebo orally twice daily for 5 days. Early detection of infection and early intervention with antibiotics will help to decrease perinatal morbidity and mortality.

During the course of your participation in this study, you may experience certain side -effects like diarrhea, nausea, vomiting, dermatitis and urticaria, which are usually mild and subside with or without treatment. It will be helpful for the pregnant women at risk to get early detection of infection and early intervention with antibiotics, will help in preventing preterm labor.

Every effort will be made to protect the confidentiality of the information you provide. This means that the researchers will be careful not to let anyone who is not working on the study see the information you provide. Only Dr. Pallavi Chalasani post graduate (OBG) and Dr. M. B. Bellad, Professor (OBG) J.N.M.C., Belgaum will have access to the information collected. Results of this study may be published for scientific purposes, but your name will not be used.

If you have any questions about the study you can contact Dr. M. B. Bellad, Professor, Department of Obstetrics and Gynecology, J. N. Medical College, Belgaum. In case you need any further information regarding your rights

as a study participant, you may please contact Dr. V. D. Patil, Principal and Chairman of J. N. Medical College, Institutional Ethics Committee, Mobile No. 94481 90231.

**Statement of consent**

I, volunteer and consent to participate in this study. I have read the consent or it has been read to me .The study has been fully explained to me and I was given an opportunity to ask questions and receive answers.

Signature/thumb impression: Participant- Name:

Signature/thumb impression: Witness- Name:

Signature of the investigator-

Date:

# ANNEXURE II – DATA COLLECTION INSTRUMENT

**Title: ORAL CLINDAMYCIN FOR PREVENTION OF PRETERM LABOR IN PREGNANCIES OF 13 TO 16±1 WEEKS WITH VAGINAL PH ≥ 5 – A RANDOMIZED DOUBLE BLIND PLACEBO CONTROLLED TRIAL**

I.D. Number: ☐☐☐☐☐☐

Name of the woman: F _____ M _____ S_____

Address (Mother): H. No. _____ Street _____ Place ____

Taluka _____ District _____

Tel No: _____

Mobile No: _____

Address (Husband): H. No. _____ Street _____ Place _____

Taluka _____ District _____

Tel No: _____

Mobile No: _____

**I. SCREENING:**

1) Is the pregnant woman of 13 – 16 ± 1 wk gestation? ☐

1) Yes 2) No

2) Is it singleton pregnancy? ☐

1) Yes 2) No

3) History of antibiotic use within previous 14 days? ☐

1) No 2) Yes

4) Is there any known fetal anomaly? ☐

1) No 2) Yes

5) Is there any maternal medical complications present? ☐

1) No 2) Yes

6) If ans is yes to Q5 then specify? _____

7) Has the woman undergone cervical cerclage? ☐

1) No 2) Yes

8) Is she suffering from fever? ☐

1) No 2) Yes

9) Is the woman willing to give consent? ☐

1) Yes 2) No

10) Was consent obtained? ☐

1) Yes 2) No

11) Is the vaginal pH ≥5?

1) Yes 2) No

12) What is the vaginal pH? _____

**II. FINAL RESULT INFORMATION:** D D M M Y Y Y

13) Date of Interview ☐☐ ☐☐ ☐☐☐☐

14) Final Result: ☐

1) Eligible Participating

2) Eligible Refusal

3) Ineligible

If the answer for the above questions is 1 the woman is Eligible.

**Participant Information:**

I.D. Number: ☐☐☐☐☐☐

15) Age (years): ☐☐

16) Occupation: ☐

1) HW

2) Working

3) Laborer

4) Professional

17) Education: ☐

1) Illiterate

2) Read

3) Write

4) Primary

5) Secondary

6) Graduate

7) Post graduate

18) What type of socio economic card she has? ☐

1) White

2) Green

3) Yellow

4) Red

5) Pan (income Tax)

19) Is she having vaginal discharge? ☐

1) No 2) Yes

20) If ans to Q19 is yes is it? ☐

1) Foul smelling

2) Non foul smelling.

21) Is there history of pruritis? ☐

1) No 2) Yes

22) Was her previous cycles regular? ☐

1) Yes 2) No

23) Gravida ☐☐

24) Para ☐☐

25) Living ☐☐

26) Abortions ☐☐

27) LMP ☐☐☐☐☐☐

28) EDD ☐☐☐☐☐☐

29) Estimated period of gestation (completed weeks) ☐☐

30) Is her period of gestation (POG) according to dates corresponding to scan POG? ☐

1) Yes 2) No

According to USG EDD is? ☐☐☐☐☐☐

Previous pregnancies:

31) History of any previous preterm birth? ☐

1) Yes 2) No

32) How many preterm births? ☐

1) 1 2) 2

3) 3 4) >3

☐

33) Was it spontaneous preterm birth?

1) Yes 2) No

34) Was it induced preterm birth? ☐

1) Yes 2) No

| 36)Year of Pregnancy | 37)Duration of pregnancy | 38)Pregnancy outcome | 39)New born weight | 40)Sex | 41)Alive | 42)Current age of child | 43)Maternal complications | 44)Outcome of baby |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | 1)Full term normal delivery<br>2)Preterm normal delivery<br>3)Still birth<br>4)LSCS<br>5)Abortion<br>6)Ectopic<br>7)MTP<br>8)Others specify____ | 1)Low<br>2)Normal<br>3)Macrosomia | 1)M<br>2)F | 1)Yes<br>2)No | | 1)Anemia<br>2)APH<br>3)PPH<br>4)Toxemia(PIH)<br>5)Others<br>6)Nil | 1)Alive & Healthy<br>2)Cong.abnormality (specify)_____<br>3)Early neonatal death<br>4)Late neonatal death<br>5)Infant death<br>6)Others (specify)_____ |

**Examination:**

35) Height (in cms): ☐☐☐

36) Weight at first visit (in kgs): ☐☐☐

37) BMI ($kg/m^2$): ☐☐ . ☐☐

38) PR: ☐☐☐

39) Blood pressure

Systolic (mm of Hg) ☐☐☐

Diastolic (mm of Hg) ☐☐☐

**Systemic examination:**

40) Is cardiovascular system normal? ☐

1. Yes 2. No

☐

41) Is Respiratory system normal?

1. Yes 2.No

42) Uterus palpable per abdomen ☐

1. Yes 2.No

43) What is the fundal height _____

44) After examination is she eligible? ☐

1) Yes 2)No

If No why (specify) _____

**Investigations:**

45) Hb % ☐☐ ☐

I.D. Number: ☐☐☐☐☐☐

Is she randomized? ☐

1) Yes 2) No

46) Has she been given medication? ☐

1) Yes 2) No

47) Has she completed the course of medicine? ☐

1) Yes 2) No

If ans to Q 47 is no ,Why specify? _____

48) Did she have any side effects? ☐

1) Nausea 2) Vomiting

3) Dermatitis 4) Urticaria

5) Diarrhea

Others specify _____

49) Did she return the empty packs? ☐

1) Yes 2) No

**Outcome data:**

I .D. Number: ☐☐☐☐☐☐

50) Date of delivery? ☐☐ ☐☐ ☐☐☐☐

51) Type of delivery? ☐

1) Spontaneous

2) Induced

52) Date of weight recorded? ☐☐ ☐☐ ☐☐☐☐

53) How much did the child weight (Grams)? ☐☐☐☐

54) What was the outcome? ☐

1) Live birth

2) Stillbirth

3) Abortus

55) Mode of delivery? ☐

1) Normal vaginal

2) LSCS

3) Forceps

4) Any other specify _____

56) Period of gestation? ☐

1) Term

2) Preterm

3) Late Abortion

57) Is the baby? ☐

1) Singleton

2) Twin

58) Gender? ☐

1) Male

2) Female

9) Don't Know

59) If alive? ☐

1) Alive and healthy

2) Early neonatal death

3) Late neonatal death (if available)

Name and signature of investigator : _____ Date:

## ANNEXURE III - MASTER CHART

| Serial Number | Group | Clindamycin No. | Identification Number | Screening | | | | | | | | | | | | Final result | | Age (Years) | Occupation | Education | Socio economic status | Vaginal Discharge | Smelling | Pruiritis | Menstrual cycle | Gravida | Para | Living | Abortion | LMP | EDD | POG | | Acc. To USG EDD | Previous pregnancies | | | | Previous pregnancy outcome | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | GA 13 to 16 ±1 Week | Single pregnancy | H/o antibiotic use within 14 days | Known fata anomaly | Maternal medical complications | Complication | Cervical cerclage | Fever | Willingness for consent | Consent | Vaginal pH ≥ 5 | Vaginal pH | Date | Result | | | | | | | | | | | | | | | Estimated | Corr with scan | | Preterm | No of births | Type of labour | Type of delivery | Year | Duration |
| 3 | C | 219 | 51660 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 26.11.10 | 1 | 21 | 1 | 4 | 2 | 1 | - | 1 | 1 | 2 | 2 | 1 | 0 | 04.08.10 | 11.05.11 | 16 | 1 | 12.05.11 | 2 | - | - | - | G1 | - |
| 6 | P | 163 | 98152 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 11.10.10 | 1 | 26 | 1 | 3 | 3 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 19.07.10 | 26.04.11 | 12 | 1 | 27.04.11 | 2 | - | - | - | - | - |
| 10 | C | 93 | 1280369 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.5 | 17.04.10 | 1 | 25 | 1 | 5 | 2 | 1 | - | 1 | 1 | 2 | 1 | 1 | 0 | 21.12.10 | 28.09.10 | 16 | 1 | 27.09.10 | 2 | - | - | - | - | G1 |
| 12 | P | 41 | 1282819 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 21.04.10 | 1 | 22 | 1 | 4 | 2 | 1 | - | 1 | 1 | 2 | 0 | 0 | 1 | 23.01.10 | 30.10.10 | 16 | 1 | 08.10.10 | 2 | - | - | - | - | - |
| 13 | C | 103 | 1288923 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.5 | 21.04.10 | 1 | 30 | 1 | 4 | 3 | 1 | - | 1 | 1 | 4 | 3 | 1 | 0 | 17.12.09 | 24.09.10 | 17 | 1 | 17.09.10 | 2 | - | - | | - | G1, G2, G3 |
| 14 | C | 140 | 1311613 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 27.04.10 | 1 | 21 | 1 | 5 | 3 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 21.01.10 | 15.10.10 | 13 | 1 | 24.10.10 | 2 | - | - | - | - | - |
| 16 | P | 157 | 894952 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.0 | 28.04.10 | 1 | 20 | 1 | 5 | 3 | 1 | - | 1 | 1 | 2 | 1 | 1 | 0 | 10.01.10 | 12.10.10 | 15 | 1 | 08.10.10 | 2 | - | - | - | - | G1 |
| 19 | C | 105 | 1314918 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 03.05.10 | 1 | 24 | 1 | 5 | 4 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 22.01.10 | 29.10.10 | 14 | 1 | 26.10.10 | 2 | - | - | - | - | - |
| 22 | P | 56 | 1315203 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 03.05.10 | 1 | 20 | 1 | 4 | 3 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 26.01.10 | 30.10.10 | 13 | 1 | 28.10.10 | 2 | - | - | - | - | - |
| 23 | C | 14 | 1315124 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.0 | 03.05.10 | 1 | 19 | 1 | 4 | 3 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 07.02.10 | 14.11.10 | 12 | 1 | 09.11.10 | 2 | - | - | - | - | - |
| 25 | C | 151 | 130192 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 21.06.10 | 1 | 22 | 1 | 4 | 4 | 1 | - | 1 | 1 | 2 | 1 | 1 | 0 | 26.02.10 | 04.11.10 | 13 | 1 | 29.10.10 | 2 | - | - | | G1 | - |
| 26 | P | 38 | 1315674 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.5 | 10.05.10 | 1 | 19 | 1 | 5 | 1 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 01.02.10 | 08.11.10 | 14 | 1 | 06.01.11 | 2 | - | - | - | - | - |
| 27 | P | 60 | 1325264 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 10.05.10 | 1 | 21 | 1 | 5 | 1 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 02.02.10 | 09.11.10 | 14 | 1 | 19.11.10 | 2 | - | - | - | - | - |
| 29 | C | 119 | 1000461 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.0 | 29.04.10 | 1 | 21 | 3 | 3 | 2 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 21.01.10 | 28.10.10 | 13 | 1 | 29.10.10 | 2 | | | | - | - |
| 30 | C | 49 | 1320171 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.0 | 10.05.10 | 1 | 20 | 1 | 5 | 1 | 1 | - | 1 | 1 | 2 | 0 | 0 | 1 | 13.02.10 | 20.11.10 | 12 | 1 | 09.11.10 | 2 | - | - | - | G1 | - |
| 40 | C | 37 | 1320142 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.0 | 10.05.10 | 1 | 20 | 1 | 5 | 2 | 1 | - | 1 | 1 | 3 | 1 | 1 | 1 | 04.02.10 | 11.11.10 | 15 | 1 | 10.11.10 | 2 | - | - | - | G1,G2 | A |
| 42 | C | 25 | 1340604 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 10.06.10 | 1 | 26 | 1 | 3 | 4 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 09.10.09 | 16.07.10 | 16 | 1 | 12.07.10 | 2 | - | - | - | - | - |
| 44 | P | 16 | 1344874 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 16.06.10 | 1 | 27 | 1 | 4 | 3 | 1 | - | 1 | 1 | 2 | 1 | 1 | 0 | 08.03.10 | 15.12.10 | 14 | 1 | 01.12.10 | 2 | - | - | - | G1 | - |
| 48 | C | 43 | 1096527 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 21.06.10 | 1 | 26 | 1 | 4 | 3 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 09.03.10 | 16.01.11 | 13 | 1 | 17.01.11 | 2 | - | - | - | - | - |
| 49 | C | 42 | 1347558 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 21.06.10 | 1 | 20 | 1 | 3 | 3 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 29.03.10 | 05.12.10 | 13 | 1 | 04.12.10 | 2 | - | - | - | - | - |
| 50 | P | 19 | 1305919 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 21.06.10 | 1 | 20 | 1 | 2 | 2 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 25.02.10 | 02.12.10 | 15 | 1 | 06.12.10 | 2 | - | - | - | - | - |
| 55 | P | 216 | 1348294 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 22.06.10 | 1 | 26 | 1 | 4 | 2 | 1 | - | 1 | 1 | 2 | 1 | 1 | 0 | 25.03.10 | 18.12.10 | 16 | 1 | 19.02.10 | 2 | - | - | - | G1 | - |
| 56 | P | 12 | 1331029 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 24.06.11 | 1 | 22 | 1 | 4 | 3 | 1 | - | 1 | 1 | 2 | 1 | 1 | 0 | 24.03.10 | 01.10.11 | 13 | 1 | 08.01.11 | 2 | - | - | - | - | G1 |
| 57 | C | 13 | 1326357 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 24.06.10 | 1 | 28 | 1 | 4 | 3 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 20.02.10 | 09.11.10 | 17 | 1 | 09.11.10 | 2 | - | - | - | - | - |
| 58 | P | 22 | 1321987 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 24.06.10 | 1 | 26 | 1 | 4 | 3 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 26.02.10 | 05.12.10 | 16 | 1 | 02.12.10 | 2 | - | - | - | - | - |
| 59 | P | 39 | 1327240 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 25.06.10 | 1 | 30 | 1 | 4 | 3 | 1 | - | 1 | 1 | 3 | 2 | 2 | 0 | 02.03.10 | 09.11.10 | 15 | 1 | 10.11.10 | 2 | - | - | - | G1,G2 | - |
| 62 | P | 27 | 1331641 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 30.06.10 | 1 | 24 | 1 | 5 | 3 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 07.03.10 | 14.12.10 | 16 | 1 | 16.12.10 | 2 | - | - | - | - | - |
| 63 | C | 17 | 582436 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 30.06.10 | 1 | 25 | 2 | 5 | 3 | 1 | - | 1 | 1 | 4 | 2 | 2 | 1 | 11.03.10 | 18.12.10 | 15 | 1 | 16.12.10 | 2 | - | - | - | * | * |
| 65 | C | 26 | 965943 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 02.07.10 | 1 | 21 | 1 | 4 | 2 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 27.03.10 | 04.01.11 | 13 | 1 | 16.01.11 | 2 | - | - | - | - | - |
| 67 | P | 68 | 1356793 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 05.07.10 | 1 | 20 | 1 | 4 | 2 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 20.05.10 | 27.01.11 | 12 | 1 | 28.01.11 | 2 | - | - | - | - | - |
| 69 | P | 89 | 1353742 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 22.06.10 | 1 | 21 | 1 | 4 | 2 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 09.03.10 | 16.12.10 | 15 | 1 | 13.12.10 | 2 | - | - | - | - | - |
| 71 | P | 5 | 1246597 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 13.02.10 | 1 | 28 | 1 | 4 | 3 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 05.09.10 | 12.06.11 | 16 | 1 | 14.06.11 | 2 | - | - | - | - | - |
| 72 | P | 30 | 1325871 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 14.07.10 | 1 | 21 | 1 | 6 | 2 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 09.09.10 | 16.12.10 | 16 | 1 | 16.12.10 | 2 | - | - | - | - | - |
| 79 | C | 28 | 749246 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 20.08.10 | 1 | 21 | 1 | 5 | 4 | 1 | - | 1 | 1 | 2 | 1 | 1 | 0 | 12.05.10 | 19.02.10 | 14 | 1 | 20.02.10 | 2 | - | - | - | G1 | - |
| 80 | C | 2 | 1355049 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 13.08.10 | 1 | 22 | 1 | 4 | 1 | 1 | - | 1 | 1 | 3 | 2 | 0 | 0 | 16.05.10 | 23.02.11 | 12 | 1 | 21.02.11 | 2 | - | - | - | G1,G2 | - |
| 81 | C | 11 | 781585 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.0 | 23.08.10 | 1 | 23 | 1 | 4 | 4 | 1 | - | 1 | 1 | 2 | 1 | 1 | 0 | 05.05.10 | 22.02.11 | 15 | 1 | 20.02.11 | 2 | - | - | - | - | G1 |
| 82 | P | 23 | 1347057 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 23.08.10 | 1 | 24 | 1 | 4 | 3 | 1 | - | 1 | 1 | 2 | 0 | 0 | 1 | 12.05.10 | 08.02.11 | 14 | 1 | 04.02.11 | 2 | - | - | - | G1 | - |
| 83 | C | 44 | 1389479 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 23.08.10 | 1 | 23 | 1 | 5 | 3 | 1 | - | 1 | 1 | 3 | 2 | 2 | 0 | 11.05.10 | 18.02.11 | 14 | 1 | 16.02.11 | 2 | - | - | - | G1, G2 | - |

## ANNEXURE III - MASTER CHART

| Serial Number | Group | Clindamycin No. | Identification Number | Previous pregnancy outcome | | | | | | | Examination | | | | | | | | | | Hb (gm%) | Randomization | Medication | Course | Reason | Side effects | Empty packs | Pregnancy outcome | Causes | Mode of delivery | Indication | Birth information | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | | | | | Blood pressure | | System | | | | | | | | | | | | | | | | | | |
| | | | | Outcome | Newborn weight | Sex | Alive | Current age (Years) | Maternal complication | Outcome of baby | Height (Cms) | Weight (Kgs) | BMI (Kg/m$^2$) | PR (/Min) | SBP (mm Hg) | DBP (mm Hg) | CVS | RS | Uterus | Fundal height (Wks) | Eligibility | | | | | | | | | | | | Date | Sex | Gestational age (wks) | Weight (Kg) |
| 3 | C | 219 | 51660 | 1 | 2 | 2 | 1 | 1.5 | 6 | 1 | 150 | 49 | 21.78 | 88 | 130 | 80 | 1 | 1 | 1 | 16 | 1 | 10.20 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 18.04.11 | M | 36.5 | 2.3 |
| 6 | P | 163 | 98152 | - | - | - | - | - | - | - | 152 | 48 | 20.78 | 80 | 126 | 86 | 1 | 1 | 1 | 12 | 1 | 10.60 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 14.03.11 | F | 33.6 | 2.0 |
| 10 | C | 93 | 1280369 | 1 | 2 | 2 | 1 | 2.5 | 6 | 1 | 156 | 56 | 23.01 | 84 | 126 | 70 | 1 | 1 | 1 | 16 | 1 | 6.50 | 1 | 1 | 1 | - | - | 1 | N | - | V | PPROM | 20.09.10 | F | 38.6 | 2.3 |
| 12 | P | 41 | 1282819 | - | - | - | - | - | - | - | 155 | 52 | 21.64 | 78 | 106 | 66 | 1 | 1 | 1 | 16 | 1 | 11.50 | 1 | 1 | 1 | - | - | 1 | N | - | A | MISSED ABORT | 06.10.10 | F | 36.4 | 2.3 |
| 13 | C | 103 | 1288923 | 1,1,4, | 2,2,2 | 1,2,2 | - | 4,2,1 | 6,6,6 | 1,3,3 | 146 | 34 | 15.95 | 80 | 110 | 70 | 1 | 1 | 1 | 16 | 1 | 11.00 | 1 | 1 | 1 | - | - | 1 | N | - | LSCS | ABR | 12.09.10 | M | 39.1 | 2.6 |
| 14 | C | 140 | 1311613 | - | - | - | - | - | - | - | 150 | 38 | 16.89 | 82 | 104 | 62 | 1 | 1 | 1 | 12 | 1 | 11.10 | 1 | 1 | 1 | - | - | 1 | N | - | V | ABR | 20.10.10 | F | 39.2 | 2.5 |
| 16 | P | 157 | 894952 | 1 | 2 | 2 | 1 | 2.5 | 6 | 1 | 150 | 44 | 19.56 | 80 | 104 | 70 | 1 | 1 | 1 | 16 | 1 | 10.00 | 1 | 1 | 1 | - | - | 1 | N | - | LSCS | IUGR/OLIG | 06.10.10 | M | 39.1 | 3.0 |
| 19 | C | 105 | 1314918 | - | - | - | - | - | - | - | 160 | 48 | 18.75 | 88 | 116 | 66 | 1 | 1 | 1 | 16 | 1 | 10.20 | 1 | 1 | 1 | - | - | 1 | N | - | V | Est Pt | 5.10.10 | F | 37.4 | 3.0 |
| 22 | P | 56 | 1315203 | - | - | - | - | - | - | - | 153 | 49 | 20.93 | 80 | 110 | 70 | 1 | 1 | 1 | 12 | 1 | 10.50 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 01.08.10 | - | 18.0 | 0.5 |
| 23 | C | 14 | 1315124 | - | - | - | - | - | - | - | 150 | 48 | 21.33 | 78 | 110 | 80 | 1 | 1 | 1 | 12 | 1 | 11.40 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 07.11.10 | F | 39.0 | 2.8 |
| 25 | C | 151 | 130192 | 4 | 2 | - | 1 | 2 | 6 | 1 | 146 | 42 | 19.70 | 76 | 110 | 60 | 1 | 1 | 1 | 12 | 1 | 10.20 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 27.10.10 | M | 38.6 | 2.5 |
| 26 | P | 38 | 1315674 | - | - | - | - | - | - | - | 140 | 42 | 21.43 | 82 | 120 | 70 | 2 | 1 | 1 | 12 | 1 | 10.20 | 1 | 1 | 1 | - | - | 1 | N | - | V | PPROM | 02.01.11 | M | 39.3 | 2.5 |
| 27 | P | 60 | 1325264 | - | - | - | - | - | - | - | 142 | 44 | 21.82 | 80 | 130 | 80 | 2 | 2 | 1 | 12 | 1 | 11.40 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 07.08.10 | F | 33.0 | 1.2 |
| 29 | C | 119 | 1000461 | - | - | - | - | - | - | - | 156 | 38 | 15.61 | 84 | 120 | 84 | 1 | 1 | 1 | 12 | 1 | 8.60 | 2 | 2 | 1 | - | - | 1 | N | - | LSCS | PPROM | 13.10.10 | M | 37.0 | 2.8 |
| 30 | C | 49 | 1320171 | 5 | - | - | - | - | - | - | 146 | 42 | 19.70 | 86 | 126 | 80 | 2 | 2 | 2 | 12 | 1 | 11.80 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 16.11.10 | M | 39.3 | 3.0 |
| 40 | C | 37 | 1320142 | 5,1 | 2 | 1 | 1 | 1.5 | 6 | 1 | 150 | 41 | 18.22 | 86 | 140 | 80 | 2 | 2 | 1 | 16 | 1 | 13.10 | 1 | 1 | 1 | - | - | 1 | N | - | LSCS | ABR | 28.10.10 | F | 38.0 | 2.2 |
| 42 | C | 25 | 1340604 | - | - | - | - | - | - | - | 150 | 36 | 16.00 | 80 | 110 | 70 | 1 | 1 | 1 | 16 | 1 | 10.70 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 24.07.10 | F | 41.0 | 2.5 |
| 44 | P | 16 | 1344874 | 1 | 2 | 1 | 1 | 2 | 6 | 1 | 153 | 39 | 16.66 | 80 | 110 | 70 | 1 | 1 | 1 | 12 | 1 | 10.50 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 07.12.10 | F | 37.6 | 2.8 |
| 48 | C | 43 | 1096527 | - | - | - | - | - | - | - | 156 | 42 | 17.26 | 84 | 110 | 74 | 1 | 1 | 1 | 12 | 1 | 106.00 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 10.01.11 | M | 39.0 | 2.5 |
| 49 | C | 42 | 1347558 | - | - | - | - | - | - | - | 152 | 38 | 16.45 | 80 | 110 | 70 | 1 | 1 | 1 | 12 | 1 | 11.00 | 1 | 1 | 1 | - | - | 1 | N | - | V | PPROM | 03.12.10 | F | 39.5 | 2.9 |
| 50 | P | 19 | 1305919 | - | - | - | - | - | - | - | 150 | 45 | 20.00 | 78 | 110 | 70 | 1 | 1 | 1 | 12 | 1 | 10.50 | 1 | 1 | 1 | - | - | 1 | N | - | V | IUD | 26.12.10 | F | 43.0 | 3.2 |
| 55 | P | 216 | 1348294 | 1 | 2 | 2 | 1 | 2.5 | 6 | 1 | 150 | 39 | 17.33 | 80 | 110 | 80 | 1 | 1 | 1 | 16 | 1 | 11.20 | 1 | 1 | 1 | - | - | 1 | N | - | LSCS | NPL | 28.10.10 | M | 32.5 | 1.6 |
| 56 | P | 12 | 1331029 | 1 | 2 | 2 | 1 | 2.5 | 6 | 1 | 156 | 38 | 15.61 | 80 | 110 | 70 | 1 | 1 | 1 | 12 | 1 | 11.00 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 24.12.10 | F | 38.6 | 1.9 |
| 57 | C | 13 | 1326357 | - | - | - | - | - | - | - | 154 | 55 | 23.19 | 78 | 100 | 60 | 1 | 1 | 1 | 16 | 1 | 12.00 | 1 | 1 | 1 | - | - | 1 | N | - | A | Anen | 23.11.10 | F | 42.0 | 2.5 |
| 58 | P | 22 | 1321987 | - | - | - | - | - | - | - | 156 | 45 | 18.49 | 80 | 110 | 70 | 1 | 1 | 1 | 16 | 1 | 11.00 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 13.12.10 | M | 41.3 | 2.8 |
| 59 | P | 39 | 1327240 | 1,1 | 2,2 | 2,2 | 1,1 | 6,2.5 | 6,6 | 1,1 | 155 | 50 | 20.81 | 80 | 130 | 80 | 1 | 1 | 1 | 16 | 1 | 11.20 | 1 | 1 | 1 | - | - | 1 | N | - | LSCS | FT DIST+PREV LSCS | 06.11.10 | F | 39.4 | 3.3 |
| 62 | P | 27 | 1331641 | - | - | - | - | - | - | - | 152 | 38 | 16.45 | 56 | 110 | 70 | 1 | 1 | 1 | 16 | 1 | 10.60 | 1 | 1 | 1 | - | - | 1 | N | - | LSCS | MATERN REQ | 07.12.10 | M | 39.0 | 2.2 |
| 63 | C | 17 | 582436 | * | * | * | * | * | * | * | 146 | 48 | 22.52 | 80 | 120 | 80 | 1 | 1 | 1 | 16 | 1 | 10.90 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 23.11.10 | F | 36.4 | 2.0 |
| 65 | C | 26 | 965943 | - | - | - | - | - | - | - | 155 | 67 | 27.89 | 80 | 110 | 80 | 1 | 1 | 1 | 12 | 1 | 10.20 | 1 | 1 | 1 | - | - | 1 | N | - | V | PPROM | 05.01.11 | M | 40.1 | 3.0 |
| 67 | P | 68 | 1356793 | - | - | - | - | - | - | - | 148 | 96 | 43.83 | 84 | 100 | 64 | 1 | 1 | 1 | 12 | 1 | 13.50 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 25.01.11 | F | 39.5 | 2.8 |
| 69 | P | 89 | 1353742 | - | - | - | - | - | - | - | 154 | 58 | 24.46 | 80 | 110 | 70 | 1 | 1 | 1 | 14 | 1 | 10.40 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 14.12.10 | M | 39.5 | 2.5 |
| 71 | P | 5 | 1246597 | - | - | - | - | - | - | - | 152 | 42 | 18.18 | 80 | 110 | 80 | 1 | 1 | 1 | 16 | 1 | 11.00 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 08.06.11 | F | 39.3 | 2.7 |
| 72 | P | 30 | 1325871 | - | - | - | - | - | - | - | 150 | 38 | 16.89 | 80 | 100 | 68 | 1 | 1 | 1 | 16 | 1 | 10.20 | 1 | 1 | 1 | - | - | 1 | N | - | A | - | 11.12.10 | F | 39.1 | 2.9 |
| 79 | C | 28 | 749246 | 1 | 2 | 2 | 1 | 4 | 6 | 1 | 152 | 45 | 19.48 | 87 | 110 | 70 | 1 | 1 | 1 | 14 | 1 | 12.90 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 31.01.11 | F | 37.2 | 2.5 |
| 80 | C | 2 | 1355049 | 3,3 | 1,1 | 2,2 | 2,2 | 3,1.5 | 6,6 | 5,5 | 135 | 31 | 17.01 | 78 | 120 | 80 | 1 | 1 | 1 | 12 | 1 | 11.00 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 10.02.10 | M | 29.0 | 1.7 |
| 81 | C | 11 | 781585 | 1 | 2 | 2 | 1 | 2 | 6 | 1 | 156 | 54 | 22.19 | 78 | 114 | 66 | 1 | 1 | 1 | 14 | 1 | 13.10 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 30.12.10 | F | 34.1 | 2.1 |
| 82 | P | 23 | 1347057 | 5 | - | - | - | - | - | - | 155 | 45 | 18.73 | 80 | 122 | 72 | 1 | 1 | 1 | 14 | 1 | 12.80 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 01.02.11 | F | 39.0 | 2.8 |
| 83 | C | 44 | 1389479 | 1,1 | - | - | - | - | - | - | 149 | 45 | 20.27 | 82 | 110 | 70 | 1 | 1 | 1 | 14 | 1 | 10.40 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 11.02.11 | M | 39.0 | 3.3 |

## ANNEXURE III - MASTER CHART

| Serial Number | Group | Clindamycin No. | Identification Number | Screening | | | | | | | | | | | | Final result | | Age (Years) | Occupation | Education | Socio economic status | Vaginal Discharge | Smelling | Pruiritis | Menstrual cycle | Gravida | Para | Living | Abortion | LMP | EDD | POG | | Acc. To USG EDD | Previous pregnancies | | | | Previous pregnancy outcome | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | GA 13 to 16 ±1 Week | Single pregnancy | H/o antibiotic use within 14 days | Known fata anomaly | Maternal medical complications | Complication | Cervical cerclage | Fever | Willingness for consent | Consent | Vaginal pH ≥ 5 | Vaginal pH | Date | Result | | | | | | | | | | | | | | | Estimated | Corr with scan | | Preterm | No of births | Type of labour | Type of delivery | Year | Duration |
| 84 | P | 10 | 1098196 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 30.08.10 | 1 | 20 | 1 | 4 | 2 | 1 | - | 1 | 1 | 2 | 1 | 1 | 0 | 10.06.10 | 17.03.11 | 16 | 1 | 19.03.11 | 2 | - | - | - | G1 | - |
| 85 | C | 9 | 1384600 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 30.08.10 | 1 | 22 | 1 | 4 | 2 | 1 | - | 1 | 1 | 2 | 1 | 1 | 0 | 01.06.10 | 08.03.11 | 11 | 1 | 07.03.11 | 2 | - | - | - | G1 | - |
| 86 | C | 78 | 960788 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 30.08.10 | 1 | 21 | 1 | 4 | 3 | 1 | - | 1 | 1 | 2 | 1 | 0 | 0 | 05.06.10 | 12.03.11 | 12 | 1 | 10.03.11 | 2 | - | - | - | G1 | - |
| 88 | P | 142 | 1394123 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 30.08.10 | 1 | 22 | 1 | 3 | 3 | 1 | - | 1 | 1 | 3 | 2 | 1 | 0 | 26.05.10 | 02.03.11 | 13 | 1 | 01.03.11 | 2 | - | - | - | G1,G2 | - |
| 89 | P | 72 | 794568 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 01.09.10 | 1 | 19 | 1 | 5 | 3 | 1 | - | 1 | 1 | 2 | 1 | 1 | 0 | 24.05.10 | 03.03.10 | 14 | 1 | 22.03.10 | 2 | - | - | - | - | - |
| 90 | P | 31 | 1368389 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 02.09.10 | 1 | 20 | 1 | 4 | 4 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 17.05.10 | 24.02.11 | 16 | 1 | 20.02.11 | 2 | - | - | - | - | - |
| 91 | P | 73 | 1375586 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 02.09.10 | 1 | 20 | 1 | 5 | 2 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 16.05.10 | 25.05.11 | 13 | 1 | 20.05.11 | 2 | - | - | - | - | - |
| 92 | P | 96 | 1373729 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 03.09.10 | 1 | 21 | 1 | 4 | 1 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 01.05.10 | 08.02.11 | 17 | 1 | 96.02.11 | 2 | - | - | - | - | - |
| 93 | P | 69 | 1396728 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 03.09.10 | 1 | 21 | 1 | 5 | 2 | 1 | - | 1 | 1 | 2 | 1 | 1 | 0 | 26.05.10 | 02.03.11 | 14 | 1 | 01.03.11 | 2 | - | - | - | G1 | - |
| 94 | C | 70 | 1375205 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.5 | 06.09.10 | 1 | 30 | 1 | 5 | 1 | 1 | - | 1 | 1 | 2 | 1 | 1 | 0 | 08.06.10 | 15.03.11 | 12 | 1 | 14.03.11 | 2 | - | - | - | - | - |
| 95 | P | 85 | 1394036 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 06.09.10 | 1 | 20 | 1 | 6 | 1 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 09.06.10 | 16.03.11 | 11 | 1 | 16.03.10 | 2 | - | - | - | - | - |
| 96 | P | 109 | 1389718 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.5 | 06.09.10 | 1 | 26 | 1 | 5 | 1 | 1 | - | 1 | 1 | 2 | 1 | 1 | 0 | 08.06.10 | 15.03.11 | 12 | 1 | 10.03.11 | 2 | - | - | - | G1 | - |
| 97 | P | 79 | 1023932 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.5 | 06.09.10 | 1 | 20 | 1 | 5 | 1 | 1 | - | 1 | 1 | 2 | 1 | 0 | 0 | 12.09.10 | 19.02.10 | 16 | 1 | 16.02.11 | 1 | 1 | 1 | 1 | G1 | - |
| 98 | P | 83 | 1375738 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 06.09.10 | 1 | 26 | 3 | 4 | 1 | 1 | - | 1 | 1 | 2 | 1 | 1 | 0 | 01.06.10 | 08.03.11 | 13 | 1 | 13.03.11 | 2 | - | - | - | G1 | - |
| 101 | P | 90 | 1399083 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 07.09.10 | 1 | 20 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 09.06.10 | 03.11.10 | 12 | 1 | 03.11.10 | 2 | - | - | - | - | - |
| 102 | C | 88 | 1311685 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 07.09.10 | 1 | 23 | 1 | 4 | 1 | 1 | - | 1 | 1 | 3 | 1 | 1 | 1 | 19.05.10 | 26.02.11 | 15 | 1 | 25.02.11 | 2 | - | - | - | G1,G2,G3 | - |
| 103 | C | 210 | 1398853 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 07.09.10 | 1 | 26 | 1 | 4 | 1 | 1 | - | 1 | 1 | 4 | 2 | 2 | 1 | 13.06.10 | 20.03.11 | 12 | 1 | 20.03.11 | 2 | - | - | - | G1,G2,G3 | - |
| 104 | P | 117 | 1109422 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 08.09.10 | 1 | 20 | 1 | 4 | 3 | 1 | - | 1 | 1 | 2 | 1 | 1 | 0 | 15.06.10 | 22.03.11 | 16 | 1 | 20.03.11 | 2 | - | - | - | G1 | - |
| 105 | C | 61 | 1398376 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 08.09.10 | 1 | 25 | 1 | 4 | 2 | 1 | - | 1 | 1 | 2 | 1 | 1 | 0 | 04.06.10 | 11.03.11 | 16 | 1 | 10.03.11 | 2 | - | - | - | - | - |
| 106 | P | 97 | 1386188 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 08.09.10 | 1 | 24 | 1 | 5 | 3 | 1 | - | 1 | 1 | 2 | 1 | 1 | 0 | 01.06.10 | 08.03.11 | 14 | 1 | 20.03.11 | 2 | - | - | - | G1 | - |
| 107 | P | 107 | 1381664 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 08.09.10 | 1 | 20 | 1 | 5 | 3 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 02.05.10 | 09.02.11 | 18 | 1 | 07.02.11 | 2 | - | - | - | - | - |
| 109 | C | 54 | 1400123 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 09.09.10 | 1 | 20 | 1 | 5 | 1 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 30.05.10 | 06.02.11 | 14 | 1 | 05.02.11 | 2 | - | - | - | - | - |
| 110 | C | 3 | 1387007 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 09.09.10 | 1 | 21 | 1 | 5 | 3 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 10.05.10 | 17.02.11 | 17 | 1 | 17.02.11 | 2 | - | - | - | - | - |
| 111 | P | 80 | 1400221 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.0 | 09.09.10 | 1 | 25 | 1 | 5 | 3 | 1 | - | 1 | 1 | 2 | 1 | 1 | 0 | 15.05.10 | 22.02.11 | 16 | 1 | 20.02.11 | 2 | - | - | - | G1 | - |
| 113 | C | 75 | 1385390 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 17.08.10 | 1 | 21 | 1 | 4 | 4 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 30.05.10 | 06.02.11 | 15 | 1 | 08.02.11 | 2 | - | - | - | - | - |
| 114 | P | 111 | 1392362 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 17.09.10 | 1 | 19 | 1 | 5 | 2 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 14.06.10 | 21.03.11 | 13 | 1 | 20.03.11 | 2 | - | - | - | - | - |
| 115 | C | 29 | 1404881 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.5 | 17.09.10 | 1 | 22 | 1 | 4 | 1 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 24.05.10 | 02.03.11 | 16 | 1 | 10.03.11 | 2 | - | - | - | - | - |
| 116 | C | 63 | 1367482 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 30.11.10 | 1 | 28 | 1 | 2 | 3 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 26.08.10 | 02.06.11 | 13 | 1 | 04.06.11 | 2 | - | - | - | - | - |
| 117 | C | 40 | 378582 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.5 | 17.09.10 | 1 | 22 | 1 | 5 | 2 | 1 | - | 1 | 1 | 2 | 0 | 0 | 1 | 28.05.10 | 05.03.11 | 15 | 1 | 04.03.11 | 2 | - | - | - | G1 | - |
| 118 | C | 32 | 1404847 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 17.09.10 | 1 | 19 | 1 | 4 | 1 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 13.05.10 | 20.01.11 | 18 | 1 | 22.01.11 | 2 | 1 | - | - | - | - |
| 119 | C | 1 | 1403787 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 16.09.10 | 1 | 21 | 1 | 4 | 2 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 24.06.10 | 01.04.11 | 13 | 1 | 02.09.11 | 2 | - | - | - | - | - |
| 120 | P | 116 | 1403454 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 15.09.10 | 1 | 22 | 1 | 5 | 3 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 21.05.10 | 28.02.11 | 16 | 1 | 22.02.11 | 2 | - | - | - | - | - |
| 121 | C | 141 | 1402846 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 15.09.10 | 1 | 32 | 1 | 6 | 1 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 21.06.10 | 28.03.11 | 16 | 1 | 26.03.11 | 2 | - | - | - | - | - |
| 123 | P | 118 | 1367864 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.5 | 15.09.10 | 1 | 25 | 2 | 4 | 3 | 1 | - | 1 | 1 | 2 | 1 | 1 | 0 | 15.06.10 | 22.03.11 | 13 | 1 | 22.03.11 | 2 | - | - | - | G1 | - |
| 125 | P | 46 | 1365783 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 20.09.10 | 1 | 24 | 2 | 5 | 1 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 17.05.10 | 24.02.11 | 18 | 1 | 21.02.11 | 2 | - | - | - | - | - |
| 126 | P | 64 | 1406618 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 20.09.10 | 1 | 25 | 1 | 4 | 3 | 1 | - | 1 | 1 | 2 | 1 | 1 | 0 | 02.06.10 | 13.03.11 | 15 | 1 | 13.03.11 | 2 | - | - | - | G1 | - |
| 127 | C | 55 | 1406713 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 20.09.10 | 1 | 20 | 1 | 4 | 3 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 08.07.10 | 15.04.11 | 14 | 1 | 12.04.11 | 2 | - | - | - | - | - |
| 128 | C | 82 | 1406798 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 20.09.10 | 1 | 20 | 1 | 4 | 1 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 19.06.10 | 26.03.11 | 13 | 1 | 24.03.11 | 2 | - | - | - | - | - |

## ANNEXURE III - MASTER CHART

| Serial Number | Group | Clindamycin No. | Identification Number | Previous pregnancy outcome | | | | | | | Examination | | | | | | | | | | | Hb (gm%) | Randomization | Medication | Course | Reason | Side effects | Empty packs | Pregnancy outcome | Causes | Mode of delivery | Indication | Birth information | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | | | | | Blood pressure | | System | | | | | | | | | | | | | | | | | | | | |
| | | | | Outcome | Newborn weight | Sex | Alive | Current age (Years) | Maternal complication | Outcome of baby | Height (Cms) | Weight (Kgs) | BMI (Kg/m$^2$) | PR (/Min) | SBP (mm Hg) | DBP (mm Hg) | CVS | RS | Uterus | Fundal height (Wks) | Eligibility | | | | | | | | | | | | Date | Sex | Gestational age (wks) | Weight (Kg) |
| 84 | P | 10 | 1098196 | 1 | 2 | 2 | 1 | 2 | 6 | 1 | 147 | 38 | 17.59 | 70 | 120 | 70 | 1 | 1 | 1 | 16 | 1 | 11.00 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 07.03.11 | F | 38.4 | 2.5 |
| 85 | C | 9 | 1384600 | 1 | 2 | 1 | 1 | 1 | 6 | 1 | 155 | 37 | 15.40 | 80 | 120 | 80 | 1 | 1 | 1 | 12 | 1 | 10.40 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 28.02.11 | M | 38.7 | 2.3 |
| 86 | C | 78 | 960788 | 1 | 2 | 1 | 1 | 2 | 6 | 1 | 155 | 41 | 17.07 | 78 | 110 | 70 | 1 | 1 | 1 | 12 | 1 | 12.10 | 1 | 1 | 1 | - | - | 1 | N | - | V | IUD | 05.03.11 | M | 39.0 | 2.9 |
| 88 | P | 142 | 1394123 | 2,4 | 2,2 | 2,2 | 1,2 | 3,1 | 6,6 | 1,3 | 150 | 50 | 22.22 | 80 | 110 | 70 | 1 | 1 | 1 | 12 | 1 | 9.20 | 1 | 1 | 1 | - | - | 1 | N | - | LSCS | UNCONT HTN | 22.01.11 | M | 34.2 | 1.6 |
| 89 | P | 72 | 794568 | - | - | - | - | - | - | - | 156 | 47 | 19.31 | 72 | 106 | 70 | 1 | 1 | 1 | 14 | 1 | 11.50 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 07.03.11 | M | 40.4 | 3.0 |
| 90 | P | 31 | 1368389 | - | - | - | - | - | - | - | 150 | 38 | 16.89 | 80 | 110 | 70 | 1 | 1 | 1 | 16 | 1 | 10.20 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 22.02.11 | M | 39.5 | 2.8 |
| 91 | P | 73 | 1375586 | - | - | - | - | - | - | - | 145 | 38 | 18.07 | 80 | 122 | 20 | 1 | 1 | 1 | 14 | 1 | 10.20 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 24.05.11 | M | 39.6 | 2.6 |
| 92 | P | 96 | 1373729 | - | - | - | - | - | - | - | 156 | 42 | 17.26 | 80 | 110 | 70 | 1 | 1 | 1 | 18 | 1 | 12.60 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 16.12.10 | F | 32.2 | 1.2 |
| 93 | P | 69 | 1396728 | 1 | 2 | 2 | 1 | 2 | 6 | 1 | 156 | 37 | 15.20 | 80 | 110 | 70 | 1 | 1 | 1 | 14 | 1 | 10.20 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 06.03.11 | F | 40.4 | 3.5 |
| 94 | C | 70 | 1375205 | 1 | 2 | 2 | 1 | 5 | 6 | 1 | 152 | 55 | 23.81 | 84 | 110 | 70 | 1 | 1 | 1 | 12 | 1 | 11.50 | 1 | 1 | 1 | - | - | 1 | N | - | V | PPROM | 18.03.11 | M | 40.3 | 3.2 |
| 95 | P | 85 | 1394036 | - | - | - | - | - | - | - | 154 | 38 | 16.02 | 76 | 100 | 68 | 1 | 1 | 1 | 12 | 1 | 11.60 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 01.03.11 | M | 37.6 | 3.2 |
| 96 | P | 109 | 1389718 | 5 | - | - | - | - | - | - | 156 | 38 | 15.61 | 80 | 110 | 70 | 1 | 1 | 1 | 12 | 1 | 10.20 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 09.03.11 | F | 39.1 | 2.5 |
| 97 | P | 79 | 1023932 | 3 | 1 | 2 | 2 | 1 | 6 | 2 | 152 | 42 | 18.18 | 80 | 120 | 84 | 1 | 1 | 1 | 16 | 1 | 11.00 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 16.02.11 | M | 39.4 | 2.9 |
| 98 | P | 83 | 1375738 | 1 | 2 | 2 | 1 | 6 | 6 | 1 | 146 | 34 | 15.95 | 70 | 118 | 70 | 1 | 1 | 1 | 14 | 1 | 12.90 | 1 | 1 | 1 | - | - | 1 | N | - | V | UNCONT HTN | 01.03.11 | F | 39.0 | 3.1 |
| 101 | P | 90 | 1399083 | - | - | - | - | - | - | - | 152 | 42 | 18.18 | 80 | 90 | 68 | 1 | 1 | 1 | 12 | 1 | 10.50 | 1 | 1 | 1 | - | - | 1 | N | - | LSCS | FT DIST | Ab Abr | F | 27.0 | 1.0 |
| 102 | C | 88 | 1311685 | 1,5 | 2 | 2 | 1 | 3 | 6 | 1 | 156 | 41 | 16.85 | 76 | 96 | 60 | 1 | 1 | 1 | 16 | 1 | 10.50 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 26.02.11 | F | 40.0 | 2.8 |
| 103 | C | 210 | 1398853 | 1,1,5 | 2,2 | 2,1 | 1,1 | 6,4 | 6,6 | 1,1 | 146 | 38 | 17.83 | 84 | 130 | 90 | 1 | 1 | 1 | 12 | 1 | 11.50 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 12.03.11 | F | 38.6 | 2.6 |
| 104 | P | 117 | 1109422 | 1 | 2 | 2 | 1 | 1.5 | 6 | 1 | 150 | 45 | 20.00 | 28 | 110 | 70 | 1 | 1 | 1 | 14 | 1 | 9.50 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 15.02.11 | - | 35.0 | 1.6 |
| 105 | C | 61 | 1398376 | - | - | - | - | - | - | - | 149 | 45 | 20.27 | 80 | 110 | 70 | 1 | 1 | 1 | 16 | 1 | 9.50 | 1 | 1 | 1 | - | - | 1 | N | - | LSCS | FL IND | 01.03.11 | M | 38.4 | 3.0 |
| 106 | P | 97 | 1386188 | 1 | 2 | 2 | 1 | 1.5 | 6 | 1 | 154 | 43 | 18.13 | 86 | 110 | 72 | 1 | 1 | 1 | 12 | 1 | 10.50 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 01.02.11 | M | 35.0 | 1.9 |
| 107 | P | 107 | 1381664 | - | - | - | - | - | - | - | 150 | 40 | 17.78 | 80 | 110 | 70 | 1 | 1 | 1 | 18 | 1 | 10.50 | 1 | 1 | 1 | - | - | 1 | N | - | LSCS | ABR | 06.02.11 | F | 39.4 | 3.0 |
| 109 | C | 54 | 1400123 | - | - | - | - | - | - | - | 146 | 42 | 19.70 | 72 | 110 | 70 | 1 | 1 | 1 | 14 | 1 | 10.00 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 08.02.11 | M | 40.2 | 2.8 |
| 110 | C | 3 | 1387007 | - | - | - | - | - | - | - | 146 | 42 | 19.70 | 78 | 110 | 70 | 1 | 1 | 1 | 16 | 1 | 10.20 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 29.01.11 | F | 37.2 | 3.5 |
| 111 | P | 80 | 1400221 | 1 | 2 | 2 | 1 | 2 | 6 | 5 | 150 | 56 | 24.89 | 80 | 120 | 80 | 1 | 1 | 1 | 16 | 1 | 10.20 | 1 | 1 | 1 | - | - | 1 | N | - | V | PPROM | 26.02.11 | F | 40.4 | 2.6 |
| 113 | C | 75 | 1385390 | - | - | - | - | - | - | - | 153 | 42 | 17.94 | 68 | 100 | 70 | 1 | 1 | 1 | 16 | 1 | 12.00 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 28.01.11 | F | 38.5 | 3.0 |
| 114 | P | 111 | 1392362 | - | - | - | - | - | - | - | 163 | 49 | 18.44 | 82 | 120 | 80 | 1 | 1 | 1 | 12 | 1 | 9.00 | 1 | 1 | 1 | - | - | 1 | N | - | LSCS | NPL | 18.03.11 | F | 39.4 | 2.5 |
| 115 | C | 29 | 1404881 | - | - | - | - | - | - | - | 166 | 46 | 16.69 | 86 | 122 | 70 | 1 | 1 | 1 | 16 | 1 | 9.60 | 1 | 1 | 1 | - | - | 1 | N | - | V | PPROM | 11.03.11 | F | 40.2 | 3.0 |
| 116 | C | 63 | 1367482 | - | - | - | - | - | - | - | 152 | 42 | 18.18 | 80 | 126 | 76 | 1 | 1 | 1 | 12 | 1 | 10.20 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 30.04.11 | M | 35.2 | 2.2 |
| 117 | C | 40 | 378582 | 5 | 3 mn A | - | - | - | - | - | 146 | 30 | 14.07 | 74 | 110 | 74 | 1 | 1 | 1 | 14 | 1 | 11.30 | 1 | 1 | 1 | - | - | 1 | N | - | A | MISSED ABORT | 01.11.10 | F | 26.4 | 2.0 |
| 118 | C | 32 | 1404847 | - | - | - | - | - | - | - | 166 | 42 | 15.24 | 74 | 110 | 70 | 1 | 1 | 1 | 18 | 1 | 9.60 | 1 | 1 | 1 | - | - | 1 | N | - | V | Est Pt | 08.02.11 | M | 42.4 | 3.5 |
| 119 | C | 1 | 1403787 | - | - | - | - | - | - | - | 155 | 45 | 18.73 | 78 | 130 | 70 | 1 | 1 | 1 | 14 | 1 | 10.60 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 01.04.11 | M | 40.0 | 3.0 |
| 120 | P | 116 | 1403454 | - | - | - | - | - | - | - | 150 | 45 | 20.00 | 78 | 110 | 70 | 1 | 1 | 1 | 14 | 1 | 12.00 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 20.02.11 | F | 38.6 | 2.9 |
| 121 | C | 141 | 1402846 | - | - | - | - | - | - | - | 153 | 54 | 23.07 | 86 | 110 | 70 | 1 | 1 | 1 | 16 | 1 | 10.20 | 1 | 1 | 1 | - | - | 1 | N | - | V | PPROM | 24.03.11 | M | 39.3 | 2.9 |
| 123 | P | 118 | 1367864 | 1 | 2 | 2 | 1 | 1.5 | 6 | 1 | 141 | 36 | 18.11 | 80 | 110 | 80 | 1 | 1 | 1 | 12 | 1 | 12.00 | 1 | 1 | 1 | - | - | 1 | N | - | V | UNCONT HTN | 20.03.11 | M | 39.5 | 2.6 |
| 125 | P | 46 | 1365783 | - | - | - | - | - | - | - | 158 | 39 | 15.62 | 86 | 116 | 76 | 1 | 1 | 1 | 18 | 1 | 9.00 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 06.02.11 | M | 37.3 | 2.6 |
| 126 | P | 64 | 1406618 | 4 | 2 | 2 | 1 | 1.5 | 6 | 1 | 160 | 47 | 18.36 | 80 | 100 | 70 | 1 | 1 | 1 | 16 | 1 | 9.60 | 1 | 1 | 1 | - | - | 1 | N | - | LSCS | NPL | 15.03.11 | F | 40.2 | 2.5 |
| 127 | C | 55 | 1406713 | - | - | - | - | - | - | - | 158 | 50 | 20.03 | 82 | 130 | 70 | 1 | 1 | 1 | 14 | 1 | 8.50 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 08.04.11 | F | 39.0 | 2.8 |
| 128 | C | 82 | 1406798 | - | - | - | - | - | - | - | 159 | 42 | 16.61 | 78 | 110 | 70 | 1 | 1 | 1 | 14 | 1 | 9.80 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 16.11.10 | - | 10.3 | 0.4 |

## ANNEXURE III - MASTER CHART

| Serial Number | Group | Clindamycin No. | Identification Number | Screening | | | | | | | | | | | | Final result | | Age (Years) | Occupation | Education | Socio economic status | Vaginal Discharge | Smelling | Pruiritis | Menstrual cycle | Gravida | Para | Living | Abortion | LMP | EDD | POG | | Acc. To USG EDD | Previous pregnancies | | | | Previous pregnancy outcome | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | GA 13 to 16 ±1 Week | Single pregnancy | H/o antibiotic use within 14 days | Known fata anomaly | Maternal medical complications | Complication | Cervical cerclage | Fever | Willingness for consent | Consent | Vaginal pH ≥ 5 | Vaginal pH | Date | Result | | | | | | | | | | | | | | | Estimated | Corr with scan | | Preterm | No of births | Type of labour | Type of delivery | Year | Duration |
| 128 | P | 127 | 1409046 | 1 | 1 | 1 | 1 | 1 | | 1 | 1 | 1 | 1 | 1 | 5.5 | 23.09.10 | 1 | 24 | 2 | 5 | 3 | 1 | - | 1 | 1 | 2 | 1 | 1 | 0 | 06.06.10 | 17.03.11 | 15 | 1 | 18.03.11 | 2 | | | | - | - |
| 130 | P | 47 | 1406979 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 20.09.10 | 1 | 20 | 1 | 4 | 3 | 1 | - | 1 | 1 | 2 | 1 | 1 | 0 | 14.06.10 | 21.03.11 | 13 | 1 | 21.03.10 | 2 | - | - | - | G1 | - |
| 131 | P | 213 | 1407517 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.5 | 21.09.10 | 1 | 20 | 1 | 3 | 1 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 04.06.10 | 11.03.11 | 16 | 1 | 09.03.11 | 2 | - | - | - | - | - |
| 132 | C | 35 | 1386207 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 22.09.10 | 1 | 25 | 1 | 5 | 3 | 1 | - | 1 | 1 | 2 | 1 | 1 | 0 | 30.05.10 | 06.03.11 | 16 | 1 | 06.03.11 | 2 | - | - | - | G1 | - |
| 134 | P | 203 | 99858 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 10.13.10 | 1 | 22 | 1 | 3 | 3 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 30.08.10 | 06.05.11 | 14 | 1 | 08.05.11 | 2 | - | - | - | - | - |
| 136 | P | 71 | 1245730 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 27.09.10 | 1 | 22 | 1 | 5 | 3 | 1 | - | 1 | 1 | 3 | 2 | 1 | 0 | 26.06.10 | 03.01.11 | 13 | 1 | 03.01.11 | 2 | - | - | - | G1, G2 | - |
| 137 | P | 99 | 1219992 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 27.09.10 | 1 | 30 | 1 | 5 | 3 | 1 | - | 1 | 1 | 2 | 1 | 0 | 0 | 01.07.10 | 08.04.11 | 12 | 1 | 07.04.11 | 1 | 1 | 2 | 1 | G1 | - |
| 138 | C | 36 | 1398234 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.5 | 27.09.10 | 1 | 20 | 1 | 1 | 3 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 02.07.10 | 09.04.11 | 12 | 1 | 06.04.11 | 2 | - | - | - | - | - |
| 139 | P | 180 | 99013 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.5 | 30.10.10 | 1 | 28 | 2 | 3 | 3 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 22.07.10 | 29.04.11 | 14 | 1 | 19.04.11 | 2 | - | - | - | - | - |
| 143 | P | 84 | 1363731 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 23.09.10 | 1 | 22 | 1 | 5 | 3 | 1 | - | 1 | 1 | 2 | 1 | 1 | 0 | 22.05.10 | 29.02.11 | 16 | 1 | 26.02.11 | 2 | - | - | - | G1 | - |
| 148 | P | 115 | 1396000 | 1 | 1 | 1 | 1 | 1 | | 1 | 1 | 1 | 1 | 1 | 5.5 | 01.10.10 | 1 | 21 | 1 | 5 | 2 | 1 | 2 | 1 | 1 | 2 | 0 | 0 | 1 | 27.06.10 | 03.03.11 | 13 | 1 | 02.10.11 | 1 | 1 | 1 | | - | A1 |
| 149 | P | 92 | 1412362 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 29.09.10 | 1 | 25 | 1 | 3 | 3 | 1 | - | 1 | 1 | 3 | 2 | 2 | 0 | 10.06.10 | 17.03.11 | 15 | 1 | 16.03.11 | 2 | - | - | - | G1,G2 | - |
| 157 | C | 208 | 1420509 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 11.10.10 | 1 | 27 | 1 | 4 | 3 | 1 | - | 1 | 1 | 2 | 1 | 1 | 0 | 22.06.10 | 29.03.11 | 15 | 1 | 26.03.11 | 1 | 1 | 1 | 2 | G1 | - |
| 158 | P | 165 | 1420432 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 11.10.10 | 1 | 24 | 1 | 4 | 3 | 1 | - | 1 | 1 | 2 | 1 | 1 | 0 | 04.07.10 | 11.04.11 | 14 | 1 | 09.04.11 | 2 | - | - | - | - | - |
| 159 | C | 50 | 1406840 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 08.11.10 | 1 | 26 | 1 | 4 | 2 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 03.07.10 | 10.04.11 | 18 | 1 | 08.04.11 | 2 | | | | - | - |
| 160 | P | 33 | 1415781 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 08.11.10 | 1 | 21 | 1 | 4 | 2 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 12.08.10 | 19.05.11 | 12 | 1 | 18.05.11 | 2 | - | - | - | - | - |
| 161 | C | 67 | 1438760 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.5 | 10.11.10 | 1 | 24 | 1 | 3 | 3 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 01.03.10 | 08.12.10 | 16 | 1 | 07.12.10 | 2 | - | - | - | - | - |
| 162 | P | 34 | 1413122 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 10.11.10 | 1 | 24 | 1 | 2 | 3 | 1 | - | 1 | 1 | 2 | 1 | 1 | 0 | 17.08.10 | 24.05.11 | 12 | 1 | 24.0511 | 2 | - | - | - | G1 | - |
| 163 | P | 127 | 1422022 | 1 | 1 | 1 | 1 | 1 | | 1 | 1 | 1 | 1 | 1 | 5.5 | 10.11.10 | 1 | 22 | 4 | 6 | 5 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 28.06.10 | 05.04.11 | 16 | 2 | 25.03.11 | 2 | | | | - | - |
| 164 | P | 110 | 1438976 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 10.11.10 | 1 | 23 | 1 | 2 | 3 | 1 | - | 1 | 1 | 4 | 1 | 1 | 2 | 14.06.10 | 21.09.11 | 17 | 1 | 20.09.11 | 2 | - | - | - | A1,G1, A2 | 1.5, 1, 2 mn |
| 165 | C | 59 | 1439810 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 11.11.10 | 1 | 30 | 1 | 3 | 2 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 08.08.10 | 15.05.11 | 13 | 1 | 16.05.11 | 2 | - | - | - | - | - |
| 166 | P | 114 | 1400270 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 11.11.10 | 1 | 21 | 1 | 5 | 3 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 11.07.10 | 18.05.11 | 17 | 1 | 19.05.11 | 2 | - | - | - | - | - |
| 167 | C | 8 | 1443928 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.5 | 17.11.10 | 1 | 21 | 1 | 3 | 3 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 10.08.10 | 17.05.11 | 14 | 1 | 18.05.11 | 2 | - | - | - | - | - |
| 168 | C | 48 | 1456900 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 03.12.10 | 1 | 26 | 1 | 4 | 2 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 10.09.10 | 17.06.11 | 12 | 1 | 16.06.11 | 2 | - | - | - | - | - |
| 169 | C | 104 | 1456720 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 04.12.10 | 1 | 20 | 1 | 4 | 3 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 04.08.10 | 18.05.11 | 16 | 1 | 16.05.11 | 2 | - | - | - | - | - |
| 171 | C | 143 | 72548 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 06.10.10 | 1 | 26 | 1 | 4 | 1 | 1 | - | 1 | 1 | 2 | 1 | 1 | 0 | 03.06.10 | 10.03.11 | 17 | 1 | 08.03.11 | 2 | - | - | - | - | G1 |
| 173 | C | 18 | 92545 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 02.10.10 | 1 | 29 | 3 | 3 | 3 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 19.06.10 | 26.03.11 | 15 | 1 | 24.03.11 | 2 | - | - | - | - | - |
| 175 | P | 168 | 93667 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 01.10.10 | 1 | 26 | 2 | 3 | 3 | 1 | - | 1 | 1 | 2 | 0 | 0 | 1 | 15.06.10 | 22.03.11 | 15 | 1 | 20.03.11 | 2 | - | - | - | A1 | - |
| 176 | C | 87 | 100277 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.5 | 07.10.10 | 1 | 32 | 1 | 3 | 3 | 1 | - | 1 | 1 | 2 | 1 | 1 | 0 | 12.06.10 | 19.03.11 | 16 | 1 | 16.03.11 | 2 | - | - | - | G1 | - |
| 178 | C | 126 | 99750 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 11.10.10 | 1 | 28 | 1 | 3 | 3 | 1 | - | 1 | 1 | 2 | 1 | 1 | 0 | 22.06.10 | 29.03.11 | 15 | 1 | 20.03.11 | 2 | - | - | - | G1 | - |
| 182 | C | 156 | 99664 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 26.10.10 | 1 | 22 | 2 | 3 | 3 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 19.07.10 | 26.04.11 | 17 | 1 | 20.04.11 | 2 | - | - | - | - | - |
| 183 | C | 81 | 98429 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 05.10.10 | 1 | 28 | 1 | 3 | 3 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 09.06.10 | 16.03.11 | 16 | 1 | 12.03.11 | 2 | - | - | - | - | - |
| 185 | P | 131 | 93329 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 10.10.10 | 1 | 28 | 1 | 3 | 3 | 1 | - | 1 | 1 | 2 | 1 | 1 | 0 | 14.06.10 | 20.03.11 | 16 | 1 | 19.03.11 | 2 | - | - | - | G1 | - |
| 186 | C | 155 | 93997 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 05.10.10 | 1 | 26 | 1 | 3 | 3 | 1 | - | 1 | 1 | 2 | 1 | 1 | 0 | 02.06.10 | 09.03.11 | 17 | 1 | 06.03.11 | 2 | - | - | - | G1 | - |
| 190 | P | 132 | 100396 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 22.10.10 | 1 | 32 | 2 | 3 | 3 | 1 | - | 1 | 1 | 2 | 1 | 1 | 0 | 23.06.10 | 30.03.11 | 17 | 1 | 26.03.11 | 2 | - | - | - | G1 | - |
| 191 | C | 169 | 80150 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 12.10.10 | 1 | 28 | 2 | 4 | 3 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 14.06.10 | 21.03.11 | 17 | 1 | 20.03.11 | 2 | - | - | - | - | - |
| 192 | C | 148 | 96162 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 03.10.10 | 1 | 29 | 3 | 3 | 3 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 14.06.10 | 21.03.11 | 16 | 1 | 18.03.11 | 2 | - | - | - | - | - |
| 194 | C | 153 | 95957 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 02.10.10 | 1 | 28 | 1 | 3 | 3 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 01.06.10 | 08.03.11 | 16 | 1 | 11.03.11 | 2 | - | - | - | - | - |

## ANNEXURE III - MASTER CHART

| Serial Number | Group | Clindamycin No. | Identification Number | Previous pregnancy outcome | | | | | | | Examination | | | | | | | | | | | Hb (gm%) | Randomization | Medication | Course | Reason | Side effects | Empty packs | Pregnancy outcome | Causes | Mode of delivery | Indication | Birth information | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | | | | | Blood pressure | | System | | | | | | | | | | | | | | | | | | | | |
| | | | | Outcome | Newborn weight | Sex | Alive | Current age (Years) | Maternal complication | Outcome of baby | Height (Cms) | Weight (Kgs) | BMI (Kg/m$^2$) | PR (/Min) | SBP (mm Hg) | DBP (mm Hg) | CVS | RS | Uterus | Fundal height (Wks) | Eligibility | | | | | | | | | | | | Date | Sex | Gestational age (wks) | Weight (Kg) |
| 128 | P | 127 | 1409046 | 1 | 2 | 1 | 2 | 1.5 | 6 | 1 | 155 | 54 | 22.48 | 80 | 100 | 70 | 1 | 1 | 1 | 16 | 1 | 11.60 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 09.03.11 | M | 38.6 | 2.9 |
| 130 | P | 47 | 1406979 | 1 | 2 | 2 | 1 | 2.5 | 6 | 1 | 155 | 38 | 15.82 | 80 | 110 | 80 | 1 | 1 | 1 | 14 | 1 | 11.50 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 15.03.11 | F | 39.1 | 2.9 |
| 131 | P | 213 | 1407517 | - | - | - | - | - | - | - | 146 | 42 | 19.70 | 74 | 110 | 70 | 1 | 1 | 1 | 16 | 1 | 12.50 | 1 | 1 | 1 | - | - | 1 | N | - | LSCS | NPL | 23.10.10 | - | 20.1 | 0.7 |
| 132 | C | 35 | 1386207 | 4(FD) | 2 | 2 | 1 | 7 | 6 | 1 | 148 | 64 | 29.22 | 76 | 110 | 70 | 1 | 1 | 1 | 16 | 1 | 10.00 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 03.03.11 | M | 39.4 | 2.6 |
| 134 | P | 203 | 99858 | - | - | - | - | - | - | - | 148 | 41 | 18.72 | 80 | 136 | 80 | 1 | 1 | 1 | 14 | 1 | 12.20 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 17.03.11 | M | 32.6 | 2.5 |
| 136 | P | 71 | 1245730 | 1,1 | 2,2 | 2,1 | 1,2 | 4 | 6,6 | 1,2 | 156 | 41 | 16.85 | 70 | 110 | 80 | 1 | 1 | 1 | 12 | 1 | 9.00 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 24.03.11 | F | 38.4 | 3.1 |
| 137 | P | 99 | 1219992 | 2.3 | 1 | 2 | 2 | - | 6 | FSB | 146 | 66 | 30.96 | 82 | 110 | 70 | 1 | 1 | 1 | 12 | 1 | 10.80 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 01.12.10 | M | 21.5 | 1.0 |
| 138 | C | 36 | 1398234 | - | - | - | - | - | - | - | 156 | 52 | 21.37 | 72 | 114 | 70 | 1 | 1 | 1 | 12 | 1 | 10.00 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 06.04.11 | F | 39.4 | 3.2 |
| 139 | P | 180 | 99013 | - | - | - | - | - | - | - | 148 | 36 | 16.44 | 74 | 126 | 72 | 1 | 1 | 1 | 14 | 1 | 10.60 | 1 | 1 | 1 | - | - | 1 | N | - | LSCS | POST DAT | 10.03.11 | F | 32.6 | 2.2 |
| 143 | P | 84 | 1363731 | 4 | 2 | 2 | 1 | 1 | 6 | 1 | 146 | 41 | 19.23 | 80 | 110 | 60 | 1 | 1 | 1 | 18 | 1 | 11.00 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 21.02.11 | F | 39.0 | 2.6 |
| 148 | P | 115 | 1396000 | A | - | - | - | - | - | - | 155 | 40 | 16.65 | 80 | 110 | 80 | 1 | 1 | 1 | 14 | 1 | 10.50 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 01.10.11 | M | 39.5 | 2.5 |
| 149 | P | 92 | 1412362 | 1,1 | 2,2 | 2,1 | 1,1 | 8,1.5 | 6,6 | 1,1 | 146 | 38 | 17.83 | 78 | 100 | 60 | 1 | 1 | 1 | 16 | 1 | 9.80 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 14.03.11 | M | 39.4 | 3.1 |
| 157 | C | 208 | 1420509 | 2 | 2 | 2 | 1 | 2 | 6 | 1 | 154 | 57 | 24.03 | 80 | 120 | 80 | 1 | 1 | 1 | 14 | 1 | 13.00 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 18.03.11 | F | 38.3 | 2.7 |
| 158 | P | 165 | 1420432 | - | - | - | - | - | - | - | 150 | 50 | 22.22 | 80 | 110 | 80 | 1 | 1 | 1 | 14 | 1 | 10.20 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 06.04.11 | F | 39.1 | 3.2 |
| 159 | C | 50 | 1406840 | - | - | - | - | - | - | - | 152 | 49 | 21.21 | 80 | 130 | 80 | 1 | 1 | 1 | 20 | 1 | 10.40 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 18.04.11 | M | 41.1 | 2.9 |
| 160 | P | 33 | 1415781 | - | - | - | - | - | - | - | 140 | 41 | 20.92 | 84 | 100 | 70 | 1 | 1 | 1 | 12 | 1 | 12.00 | 1 | 1 | 1 | - | - | 1 | N | - | LSCS | Not Will VBAC | 07.03.11 | F | 29.4 | 1.2 |
| 161 | C | 67 | 1438760 | - | - | - | - | - | - | - | 150 | 82 | 36.44 | 86 | 110 | 70 | 1 | 1 | 1 | 16 | 1 | 10.20 | 1 | 1 | 1 | - | - | 1 | N | - | LSCS | FT DIST | 06.12.10 | F | 39.5 | 2.9 |
| 162 | P | 34 | 1413122 | 4 | 2 | 1 | 1 | 3 | 6 | 1 | 154 | 44 | 18.55 | 76 | 110 | 84 | 1 | 1 | 1 | 12 | 1 | 11.60 | 1 | 1 | 1 | - | - | 1 | N | - | V | PPROM | 06.07.11 | F | 37.3 | 2.6 |
| 163 | P | 127 | 1422022 | - | - | - | - | - | - | - | 162 | 46 | 17.53 | 80 | 126 | 80 | 1 | 1 | 1 | 16 | 1 | 8.50 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 28.03.11 | M | 39.0 | 3.1 |
| 164 | P | 110 | 1438976 | - | - | - | - | - | - | - | 156 | 42 | 17.26 | 74 | 140 | 84 | 1 | 1 | 1 | 18 | 1 | 12.50 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 06.04.11 | F | 37.6 | 2.7 |
| 165 | C | 59 | 1439810 | - | - | - | - | - | - | - | 148 | 46 | 21.00 | 80 | 110 | 70 | 1 | 1 | 1 | 12 | 1 | 11.20 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 20.03.11 | F | 32.0 | 1.2 |
| 166 | P | 114 | 1400270 | - | - | - | - | - | - | - | 150 | 48 | 21.33 | 78 | 110 | 70 | 1 | 1 | 1 | 16 | 1 | 10.00 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 31.03.11 | M | 33.1 | 1.9 |
| 167 | C | 8 | 1443928 | - | - | - | - | - | - | - | 146 | 52 | 24.39 | 66 | 110 | 70 | 1 | 1 | 1 | 14 | 1 | 10.50 | 1 | 1 | 1 | - | - | 1 | N | - | V | Est Pt | 15.05.11 | F | 39.5 | 3.0 |
| 168 | C | 48 | 1456900 | - | - | - | - | - | - | - | 152 | 48 | 20.78 | 80 | 110 | 70 | 1 | 1 | 1 | 12 | 1 | 11.00 | 1 | 1 | 1 | - | - | 1 | N | - | LSCS | PRECIOUS PREG | 03.06.11 | M | 38.0 | 2.2 |
| 169 | C | 104 | 1456720 | - | - | - | - | - | - | - | 155 | 42 | 17.48 | 84 | 130 | 80 | 1 | 1 | 1 | 16 | 1 | 10.20 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 31.05.11 | F | 41.6 | 3.5 |
| 171 | C | 143 | 72548 | 1 | 2 | 2 | 1 | 3.5 | 6 | 1 | 156 | 54 | 22.19 | 80 | 110 | 70 | 1 | 1 | 1 | 16 | 1 | 10.20 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 03.03.11 | F | 39.0 | 3.4 |
| 173 | C | 18 | 92545 | - | - | - | - | - | - | - | 152 | 40 | 17.31 | 82 | 126 | 74 | 1 | 1 | 1 | 16 | 1 | 10.60 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 22.03.11 | F | 39.3 | 2.4 |
| 175 | P | 168 | 93667 | 5 | 2.5 mn A | - | - | - | - | - | 158 | 36 | 14.42 | 86 | 110 | 74 | 1 | 1 | 1 | 16 | 1 | 9.20 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 15.03.11 | M | 39.0 | 2.4 |
| 176 | C | 87 | 100277 | 1 | 2 | 2 | 1 | 3 | 6 | 1 | 152 | 45 | 19.48 | 86 | 130 | 90 | 1 | 1 | 1 | 16 | 1 | 10.20 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 21.03.11 | M | 40.2 | 2.8 |
| 178 | C | 126 | 99750 | 1 | 2 | 1 | 1 | 2 | 6 | 1 | 140 | 56 | 28.57 | 86 | 120 | 84 | 1 | 1 | 1 | 16 | 1 | 12.10 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 17.03.11 | M | 38.2 | 3.2 |
| 182 | C | 156 | 99664 | - | - | - | - | - | - | - | 148 | 42 | 19.17 | 80 | 120 | 74 | 1 | 1 | 1 | 16 | 1 | 9.60 | 1 | 1 | 1 | - | - | 1 | N | - | V | Est Pt | 08.03.11 | M | 33.0 | 1.9 |
| 183 | C | 81 | 98429 | - | - | - | - | - | - | - | 159 | 54 | 21.36 | 86 | 110 | 74 | 1 | 1 | 1 | 16 | 1 | 8.60 | 1 | 1 | 1 | - | - | 1 | N | - | LSCS | ECL | 07.03.11 | M | 38.5 | 2.9 |
| 185 | P | 131 | 93329 | 4 | 2 | 2 | 1 | 1.5 | 6 | 1 | 148 | 36 | 16.44 | 84 | 112 | 76 | 1 | 1 | 1 | 16 | 1 | 11.60 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 09.03.11 | M | 38.3 | 3.3 |
| 186 | C | 155 | 93997 | 1 | 2 | 2 | 1 | 1.5 | 6 | 1 | 152 | 48 | 20.78 | 76 | 126 | 86 | 1 | 1 | 1 | 16 | 1 | 13.10 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 15.03.11 | M | 41.0 | 2.4 |
| 190 | P | 132 | 100396 | 1 | 2 | 2 | 2.5 | - | 6 | 1 | 152 | 42 | 18.18 | 86 | 130 | 84 | 1 | 1 | 1 | 16 | 1 | 13.60 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 24.03.11 | M | 40.6 | 3.2 |
| 191 | C | 169 | 80150 | - | - | - | - | - | - | - | 146 | 46 | 21.58 | 80 | 120 | 84 | 1 | 1 | 1 | 16 | 1 | 11.20 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 14.03.11 | M | 39.0 | 2.3 |
| 192 | C | 148 | 96162 | - | - | - | - | - | - | - | 142 | 51 | 25.29 | 86 | 110 | 70 | 1 | 1 | 1 | 16 | 1 | 10.60 | 1 | 1 | 1 | - | - | 1 | N | - | LSCS | PPROM | 16.03.11 | M | 39.2 | 3.0 |
| 194 | C | 153 | 95957 | - | - | - | - | - | - | - | 138 | 48 | 25.20 | 80 | 112 | 76 | 1 | 1 | 1 | 10 | 1 | 8.40 | 1 | 1 | 1 | - | - | 1 | N | - | LSCS | PREV 2 LSCS | 07.03.11 | M | 39.6 | 2.6 |

## ANNEXURE III - MASTER CHART

| Serial Number | Group | Clindamycin No. | Identification Number | Screening | | | | | | | | | | | | Final result | | Age (Years) | Occupation | Education | Socio economic status | Vaginal Discharge | Smelling | Pruiritis | Menstrual cycle | Gravida | Para | Living | Abortion | LMP | EDD | POG | | Acc. To USG EDD | Previous pregnancies | | | | Previous pregnancy outcome | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | GA 13 to 16 ±1 Week | Single pregnancy | H/o antibiotic use within 14 days | Known fata anomaly | Maternal medical complications | Complication | Cervical cerclage | Fever | Willingness for consent | Consent | Vaginal pH ≥ 5 | Vaginal pH | Date | Result | | | | | | | | | | | | | | | Estimated | Corr with scan | | Preterm | No of births | Type of labour | Type of delivery | Year | Duration |
| 195 | C | 146 | 97839 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 10.10.10 | 1 | 25 | 1 | 2 | 1 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 15.06.10 | 22.03.11 | 16 | 1 | 20.03.11 | 2 | - | - | - | - | - |
| 196 | P | 182 | 69679 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 12.10.10 | 1 | 29 | 1 | 3 | 3 | 1 | - | 1 | 1 | 2 | 0 | 0 | 1 | 09.06.10 | 16.03.11 | 16 | 1 | 12.03.11 | 2 | - | - | - | A1 | - |
| 199 | C | 160 | 95644 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 12.11.10 | 1 | 22 | 1 | 5 | 2 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 11.08.10 | 18.05.11 | 14 | 1 | 20.05.11 | 2 | - | - | - | - | - |
| 202 | C | 74 | 1438609 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 05.01.11 | 1 | 28 | 1 | 3 | 3 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 30.09.10 | 07.06.11 | 13 | 1 | 06.06.11 | 2 | - | - | - | - | - |
| 206 | P | 6 | 1460612 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 05.01.11 | 1 | 24 | 1 | 3 | 3 | 1 | - | 1 | 1 | 3 | 2 | 2 | 0 | 17.10.10 | 24.07.11 | 11 | 1 | 24.07.11 | 2 | - | - | - | G1, G2 | - |
| 210 | C | 100 | 1452290 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 29.11.10 | 1 | 23 | 1 | 3 | 3 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 29.08.10 | 05.06.11 | 13 | 1 | 05.06.11 | 2 | - | - | - | - | - |
| 214 | P | 137 | 1513670 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 31.01.11 | 1 | 24 | 1 | 4 | 3 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 06.10.10 | 13.07.11 | 16 | 1 | 15.07.11 | 2 | - | - | - | - | - |
| 215 | P | 130 | 1499061 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 31.01.11 | 1 | 20 | 1 | 4 | 1 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 05.10.10 | 12.07.11 | 14 | 1 | 10.07.11 | 2 | - | - | - | - | - |
| 216 | P | 133 | 1471247 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 31.01.11 | 1 | 26 | 1 | 7 | 3 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 16.10.10 | 23.07.11 | 15 | 1 | 20.07.11 | 2 | - | - | - | - | - |
| 225 | C | 108 | 1472764 | 1 | 1 | 1 | 1 | 1 | | 1 | 1 | 1 | 1 | 1 | 5.5 | 10.02.11 | 1 | 26 | 1 | 3 | 3 | 1 | - | 1 | 1 | 3 | 1 | 1 | 1 | 02.10.10 | 09.07.11 | 16 | 1 | 08.07.11 | 2 | | | | G1, A1 | 2 mn A |
| 231 | C | 53 | 1529559 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 14.02.11 | 1 | 26 | 1 | 4 | 3 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 10.11.10 | 17.08.11 | 13 | 1 | 16.08.11 | 2 | - | - | - | - | - |
| 232 | C | 77 | 1533773 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 17.02.11 | 1 | 31 | 1 | 3 | 3 | 1 | - | 1 | 1 | 2 | 1 | 1 | 0 | 04.11.10 | 11.08.11 | 15 | 1 | 12.08.11 | 2 | - | - | - | G1 | - |
| 234 | C | 176 | 97228 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.0 | 01.10.10 | 1 | 27 | 1 | 2 | 2 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 09.07.10 | 10.04.11 | 16 | 1 | 20.04.11 | 2 | - | - | - | - | - |
| 236 | C | 125 | 1496098 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 24.02.11 | 1 | 35 | 1 | 2 | 3 | 1 | - | 1 | 1 | 3 | 2 | 2 | 0 | 09.11.10 | 16.08.11 | 15 | 1 | 16.08.11 | 2 | - | - | - | G1,G2 | - |
| 240 | C | 220 | 1447374 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.5 | 22.11.10 | 1 | 21 | 2 | 4 | 3 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 18.08.10 | 25.05.11 | 13 | 1 | 06.06.11 | 2 | - | - | - | - | - |
| 241 | C | 20 | 1449234 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.5 | 11.12.10 | 1 | 22 | 2 | 3 | 3 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 03.09.10 | 10.06.11 | 14 | 1 | 16.06.11 | 2 | - | - | - | - | - |
| 244 | C | 120 | 1542993 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.5 | 24.02.11 | 1 | 23 | 1 | 2 | 3 | 1 | - | 1 | 1 | 3 | 2 | 2 | 0 | 23.10.10 | 30.07.11 | 12 | 1 | 29.07.11 | 2 | - | - | - | G1,G2 | - |
| 245 | C | 121 | 1545654 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 26.02.11 | 1 | 22 | 1 | 4 | 3 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 23.10.10 | 31.07.11 | 18 | 1 | 30.07.11 | 2 | - | - | - | - | - |
| 246 | P | 123 | 1505864 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 26.02.11 | 1 | 26 | 2 | 3 | 3 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 02.11.10 | 09.08.11 | 16 | 1 | 15.08.11 | 2 | - | - | - | - | - |
| 260 | C | 212 | 93347 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 28.10.10 | 1 | 29 | 1 | 1 | 1 | 1 | - | 1 | 1 | 3 | 1 | 1 | 1 | 09.07.10 | 16.04.11 | 15 | 1 | 08.04.11 | 2 | - | - | - | G1,G2 | 3 mn A |
| 266 | C | 15 | 1550339 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 03.03.11 | 1 | 22 | 2 | 4 | 3 | 1 | - | 1 | 1 | 2 | 1 | 1 | 0 | 10.10.10 | 17.07.11 | 18 | 1 | 10.07.11 | 2 | - | - | - | - | G1 |
| 267 | C | 106 | 1582579 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.2 | 31.03.11 | 1 | 23 | 2 | 3 | 3 | 1 | - | 1 | 1 | 2 | 1 | 1 | 0 | 27.12.10 | 03.09.11 | 13 | 1 | 06.09.11 | 2 | - | - | - | G1 | - |
| 270 | P | 172 | 95362 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 20.11.10 | 1 | 25 | 1 | 5 | 2 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 07.09.10 | 14.06.11 | 13 | 1 | 10.06.11 | 2 | - | - | - | - | - |
| 273 | C | 135 | 62278 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 14.12.10 | 1 | 29 | 3 | 3 | 3 | 1 | - | 1 | 1 | 2 | 1 | 1 | 0 | 05.09.10 | 12.06.11 | 18 | 1 | 10.06.11 | 2 | - | - | - | - | G1 |
| 274 | C | 222 | 94221 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 30.10.10 | 1 | 28 | 1 | 2 | 3 | 1 | - | 1 | 1 | 2 | 1 | 1 | 0 | 05.07.10 | 12.04.11 | 16 | 1 | 19.04.11 | 2 | - | - | - | G1 | - |
| 280 | C | 174 | 93757 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 01.12.10 | 1 | 26 | 1 | 4 | 1 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 02.09.10 | 11.07.11 | 12 | 1 | 06.07.11 | 2 | - | - | - | - | - |
| 284 | C | 209 | 62504 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 23.11.10 | 1 | 28 | 1 | 4 | 2 | 1 | - | 1 | 1 | 2 | 1 | 1 | 0 | 15.08.10 | 22.05.11 | 14 | 1 | 20.05.11 | 2 | - | - | - | - | - |
| 291 | C | 192 | 94938 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 25.11.10 | 1 | 24 | 1 | 5 | 2 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 22.07.10 | 29.04.11 | 16 | 1 | 28.04.11 | 2 | - | - | - | - | - |
| 295 | P | 158 | 93995 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 18.11.10 | 1 | 24 | 1 | 4 | 2 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 06.07.10 | 13.04.11 | 18 | 1 | 10.09.11 | 2 | - | - | - | - | - |
| 298 | C | 215 | 94754 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 15.11.10 | 1 | 28 | 1 | 5 | 3 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 14.07.10 | 21.04.11 | 17 | 1 | 15.04.11 | 2 | - | - | - | - | - |
| 315 | P | 57 | 1592546 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.0 | 09.04.11 | 1 | 21 | 1 | 4 | 1 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 09.12.10 | 16.09.11 | 17 | 1 | 12.09.11 | 2 | - | - | - | - | - |
| 316 | C | 134 | 1538269 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 21.02.11 | 1 | 25 | 1 | 2 | 3 | 1 | - | 1 | 1 | 3 | 1 | 1 | 1 | 09.09.10 | 16.06.11 | 13 | 1 | 17.06.11 | 1 | 1 | 2 | 1 | - | 5 mn A |
| 320 | P | 139 | 1624743 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 07.05.11 | 1 | 30 | 2 | 2 | 2 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 15.01.11 | 22.10.11 | 15 | 1 | 16.10.11 | 2 | - | - | - | - | - |
| 321 | P | 138 | 1505943 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 22.01.11 | 1 | 26 | 1 | 7 | 1 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 17.09.10 | 24.06.11 | 17 | 1 | 20.06.11 | 2 | - | - | - | - | - |
| 324 | C | 136 | 1550286 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 03.03.11 | 1 | 20 | 1 | 3 | 3 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 04.11.10 | 11.08.11 | 17 | 1 | 09.08.11 | 2 | - | - | - | - | - |
| 348 | C | 21 | 370281 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 16.06.10 | 1 | 28 | 1 | 4 | 1 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 20.03.10 | 27.12.10 | 12 | 1 | 22.12.10 | 2 | - | - | - | - | - |
| 366 | P | 129 | 101416 | 1 | 1 | 1 | 1 | 1 | | 1 | 1 | 1 | 1 | 1 | 6.0 | 07.02.11 | 1 | 22 | 1 | 2 | 3 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 23.11.10 | 30.08.11 | 15 | 1 | 26.08.11 | 2 | | | | - | - |
| 399 | P | 95 | 1376191 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 07.09.10 | 1 | 22 | 1 | 4 | 1 | 1 | - | 1 | 1 | 2 | 1 | 1 | 0 | 04.05.10 | 11.02.11 | 18 | 1 | 10.02.11 | 2 | - | - | - | G1 | - |

## ANNEXURE III - MASTER CHART

| Serial Number | Group | Clindamycin No. | Identification Number | Previous pregnancy outcome | | | | | | | Examination | | | | | | | | | | | Hb (gm%) | Randomization | Medication | Course | Reason | Side effects | Empty packs | Pregnancy outcome | Causes | Mode of delivery | Indication | Birth information | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | | | | | Blood pressure | | System | | | | | | | | | | | | | | | | | | | | |
| | | | | Outcome | Newborn weight | Sex | Alive | Current age (Years) | Maternal complication | Outcome of baby | Height (Cms) | Weight (Kgs) | BMI (Kg/m$^2$) | PR (/Min) | SBP (mm Hg) | DBP (mm Hg) | CVS | RS | Uterus | Fundal height (Wks) | Eligibility | | | | | | | | | | | | Date | Sex | Gestational age (wks) | Weight (Kg) |
| 195 | C | 146 | 97839 | - | - | - | - | - | - | - | 161 | 58 | 22.38 | 86 | 110 | 70 | 1 | 1 | 1 | 16 | 1 | 10.60 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 15.03.11 | M | 39.0 | 2.6 |
| 196 | P | 182 | 69679 | 3 mn A | - | - | - | - | - | - | 156 | 46 | 18.90 | 86 | 126 | 88 | 1 | 1 | 1 | 16 | 1 | 13.60 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 01.03.11 | M | 37.6 | 3.2 |
| 199 | C | 160 | 95644 | - | - | - | - | - | - | - | 156 | 44 | 17.87 | 74 | 110 | 70 | 1 | 1 | 1 | 14 | 1 | 10.60 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 30.04.11 | M | 37.3 | 2.2 |
| 202 | C | 74 | 1438609 | - | - | - | - | - | - | - | 156 | 46 | 18.90 | 86 | 116 | 74 | 1 | 1 | 1 | 14 | 1 | 11.00 | 1 | 1 | 1 | - | - | 1 | N | - | LSCS | Br | 26.05.11 | F | 38.3 | 3.0 |
| 206 | P | 6 | 1460612 | 1,1 | 2,2 | 2,1 | 1,1 | 5,1.5 | 6 | 1,1 | 150 | 39 | 17.33 | 80 | 116 | 70 | 1 | 1 | 2 | 12 | 1 | 11.00 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 26.06.11 | M | 36.0 | 2.8 |
| 210 | C | 100 | 1452290 | - | - | - | - | - | - | - | 160 | 50 | 19.53 | 80 | 110 | 80 | 1 | 1 | 1 | 12 | 1 | 9.50 | 1 | 1 | 1 | - | - | 1 | N | - | V | PPROM | 01.06.11 | F | 39.3 | 3.1 |
| 214 | P | 137 | 1513670 | - | - | - | - | - | - | - | 152 | 44 | 19.04 | 80 | 120 | 80 | 1 | 1 | 1 | 16 | 1 | 10.20 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 10.07.11 | M | 39.4 | 3.0 |
| 215 | P | 130 | 1499061 | - | - | - | - | - | - | - | 160 | 49 | 19.14 | 78 | 110 | 80 | 1 | 1 | 1 | 14 | 1 | 10.20 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 12.07.11 | M | 40.0 | 2.5 |
| 216 | P | 133 | 1471247 | - | - | - | - | - | - | - | 148 | 34 | 15.52 | 80 | 110 | 70 | 1 | 1 | 1 | 16 | 1 | 10.80 | 1 | 1 | 1 | - | - | 1 | N | - | LSCS | OLIG | 29.07.11 | M | 39.1 | 3.0 |
| 225 | C | 108 | 1472764 | 1 | 2 | 2 | 1 | 2.5 | 6 | 1 | 165 | 45 | 16.53 | 86 | 118 | 68 | 1 | 1 | 1 | 16 | 1 | 10.80 | 1 | 1 | 1 | - | - | 1 | N | - | V | UNCONT HTN | 14.07.11 | F | 40.5 | 2.9 |
| 231 | C | 53 | 1529559 | - | - | - | - | - | - | - | 152 | 48 | 20.78 | 84 | 116 | 70 | 1 | 1 | 1 | 12 | 1 | 9.80 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 12.08.11 | F | 39.2 | 2.3 |
| 232 | C | 77 | 1533773 | 1 | 2 | 2 | 1 | 4 | 6 | 1 | 159 | 57 | 22.55 | 64 | 110 | 80 | 1 | 1 | 1 | 16 | 1 | 11.30 | 1 | 1 | 1 | - | - | 1 | N | - | V | ECL | 30.07.11 | F | 38.2 | 3.1 |
| 234 | C | 176 | 97228 | - | - | - | - | - | - | - | 148 | 36 | 16.44 | 80 | 100 | 60 | 1 | 1 | 1 | 16 | 1 | 13.00 | 1 | 1 | 1 | - | - | 1 | N | - | LSCS | PPROM | 04.04.11 | M | 38.2 | 2.6 |
| 236 | C | 125 | 1496098 | 1,4 | 2,2 | 2,2 | 1,1 | 13,9 | 6,6 | 1,1 | 156 | 35 | 14.38 | 80 | 110 | 70 | 1 | 1 | 1 | 14 | 1 | 8.00 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 23.07.11 | M | 36.4 | 2.3 |
| 240 | C | 220 | 1447374 | - | - | - | - | - | - | - | 152 | 40 | 17.31 | 80 | 110 | 74 | 1 | 1 | 1 | 12 | 1 | 10.50 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 20.04.11 | F | 35.0 | 2.0 |
| 241 | C | 20 | 1449234 | - | - | - | - | - | - | - | 152 | 53 | 22.94 | 80 | 116 | 70 | 1 | 1 | 1 | 12 | 1 | 10.50 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 02.06.11 | F | 38.6 | 3.6 |
| 244 | C | 120 | 1542993 | 1,1 | 2,2 | 2,1 | 1,1 | 5,2 | 6,6 | 1,1 | 153 | 33 | 14.10 | 86 | 110 | 70 | 1 | 1 | 1 | 12 | 1 | 11.20 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 25.07.11 | F | 39.2 | 2.5 |
| 245 | C | 121 | 1545654 | - | - | - | - | - | - | - | 152 | 55 | 23.81 | 80 | 110 | 68 | 1 | 1 | 1 | 18 | 1 | 10.20 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 30.07.11 | F | 39.6 | 2.7 |
| 246 | P | 123 | 1505864 | - | - | - | - | - | - | - | 152 | 54 | 23.37 | 84 | 120 | 80 | 1 | 1 | 1 | 16 | 1 | 11.50 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 16.08.11 | F | 40.1 | 3.4 |
| 260 | C | 212 | 93347 | 1 | 2 | 2 | 1 | 1.5 | 6 | 1 | 156 | 49 | 20.13 | 84 | 130 | 68 | 1 | 1 | 1 | 16 | 1 | 13.10 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 07.04.11 | M | 38.5 | 2.9 |
| 266 | C | 15 | 1550339 | 4 | 2 | 2 | 1 | 2 | 6 | 1 | 150 | 45 | 20.00 | 80 | 120 | 72 | 1 | 1 | 1 | 18 | 1 | 102.00 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 21.06.11 | M | 36.6 | 3.0 |
| 267 | C | 106 | 1582579 | 4 | 2 | 1 | 1 | 2 | 6 | 1 | 150 | 46 | 20.44 | 80 | 116 | 84 | 1 | 1 | 1 | 12 | 1 | 10.60 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 01.09.11 | F | 39.5 | 2.8 |
| 270 | P | 172 | 95362 | - | - | - | - | - | - | - | 155 | 48 | 19.98 | 84 | 110 | 80 | 1 | 1 | 1 | 12 | 1 | 11.00 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 02.06.11 | F | 38.2 | 3.6 |
| 273 | C | 135 | 62278 | 1 | 2 | 1 | 1 | 2 | 6 | 1 | 150 | 38 | 16.89 | 76 | 100 | 64 | 1 | 1 | 1 | 18 | 1 | 12.20 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 12.06.11 | M | 40.0 | 3.4 |
| 274 | C | 222 | 94221 | 1 | 2 | 1 | 1 | 1.5 | 6 | 1 | 152 | 36 | 15.58 | 80 | 120 | 84 | 1 | 1 | 1 | 16 | 1 | 12.60 | 1 | 1 | 1 | - | - | 1 | N | - | LSCS | IUGR | 09.04.11 | F | 39.4 | 2.7 |
| 280 | C | 174 | 93757 | - | - | - | - | - | - | - | 156 | 58 | 23.83 | 84 | 130 | 80 | 1 | 1 | 1 | 12 | 1 | 11.90 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 01.07.11 | F | 38.4 | 2.7 |
| 284 | C | 209 | 62504 | - | - | - | - | - | - | - | 156 | 52 | 21.37 | 86 | 130 | 70 | 1 | 1 | 1 | 14 | 1 | 12.00 | 1 | 1 | 1 | - | - | 1 | N | - | LSCS | Not Will VBAC | 26.05.11 | M | 40.4 | 3.5 |
| 291 | C | 192 | 94938 | - | - | - | - | - | - | - | 156 | 50 | 20.55 | 84 | 110 | 70 | 1 | 1 | 1 | 16 | 1 | 11.50 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 23.04.11 | M | 39.0 | 2.3 |
| 295 | P | 158 | 93995 | - | - | - | - | - | - | - | 153 | 50 | 21.36 | 90 | 110 | 80 | 1 | 1 | 1 | 16 | 1 | 10.50 | 1 | 1 | 1 | - | - | 1 | N | - | LSCS | FT DIST | 10.04.11 | M | 39.4 | 3.5 |
| 298 | C | 215 | 94754 | - | - | - | - | - | - | - | 158 | 61 | 24.23 | 76 | 120 | 70 | 1 | 1 | 1 | 16 | 1 | 11.50 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 04.04.11 | M | 37.4 | 2.7 |
| 315 | P | 57 | 1592546 | - | - | - | - | - | - | - | 150 | 41 | 18.22 | 84 | 120 | 84 | 1 | 1 | 1 | 16 | 1 | 12.90 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 04.09.11 | F | 38.2 | 2.8 |
| 316 | C | 134 | 1538269 | 2 | 2 | 1 | 1 | 4 | 6 | 1 | 150 | 36 | 16.00 | 80 | 110 | 76 | 1 | 1 | 1 | 12 | 1 | 10.20 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 07.06.11 | M | 38.5 | 2.7 |
| 320 | P | 139 | 1624743 | - | - | - | - | - | - | - | 152 | 67 | 29.00 | 80 | 110 | 70 | 1 | 1 | 1 | 16 | 1 | 10.00 | 1 | 1 | 1 | - | - | 1 | N | - | LSCS | NPL | 21.10.11 | M | 40.0 | 2.8 |
| 321 | P | 138 | 1505943 | - | - | - | - | - | - | - | 152 | 45 | 19.48 | 80 | 152 | 80 | 1 | 1 | 1 | 16 | 1 | 102.00 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 10.06.11 | F | 38.0 | 3.1 |
| 324 | C | 136 | 1550286 | - | - | - | - | - | - | - | 152 | 50 | 21.64 | 80 | 110 | 70 | 1 | 1 | 1 | 18 | 1 | 10.20 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 21.07.11 | F | 37.0 | 2.9 |
| 348 | C | 21 | 370281 | - | - | - | - | - | - | - | 156 | 48 | 19.72 | 76 | 110 | 70 | 1 | 1 | 2 | 12 | 1 | 13.30 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 19.12.10 | F | 38.6 | 3.0 |
| 366 | P | 129 | 101416 | - | - | - | - | - | - | - | 148 | 52 | 23.74 | 74 | 126 | 74 | 1 | 1 | 1 | 16 | 1 | 10.60 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 24.08.11 | M | 39.1 | 2.5 |
| 399 | P | 95 | 1376191 | 1 | 2 | 2 | 1 | 1.5 | 6 | 1 | 152 | 47 | 20.34 | 88 | 120 | 70 | 1 | 1 | 1 | 18 | 1 | 11.10 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 07.02.11 | M | 39.3 | 3.0 |

## ANNEXURE III - MASTER CHART

| Serial Number | Group | Clindamycin No. | Identification Number | Screening | | | | | | | | | | | | Final result | | Age (Years) | Occupation | Education | Socio economic status | Vaginal Discharge | Smelling | Pruiritis | Menstrual cycle | Gravida | Para | Living | Abortion | LMP | EDD | POG | | Acc. To USG EDD | Previous pregnancies | | | | Previous pregnancy outcome | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | GA 13 to 16 ±1 Week | Single pregnancy | H/o antibiotic use within 14 days | Known fata anomaly | Maternal medical complications | Complication | Cervical cerclage | Fever | Willingness for consent | Consent | Vaginal pH ≥ 5 | Vaginal pH | Date | Result | | | | | | | | | | | | | | | Estimated | Corr with scan | | Preterm | No of births | Type of labour | Type of delivery | Year | Duration |
| 400 | P | 144 | 1561786 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 12.03.11 | 1 | 24 | 1 | 3 | 2 | 1 | - | 1 | 1 | 3 | 2 | 2 | 0 | 04.10.10 | 11.07.11 | 16 | 1 | 10.07.11 | 2 | - | - | - | G1,G2 | - |
| 401 | P | 181 | 1538586 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 21.02.11 | 1 | 24 | 1 | 3 | 1 | 1 | - | 1 | 1 | 2 | 1 | 1 | 0 | 17.09.10 | 24.06.11 | 18 | 1 | 20.06.11 | 2 | - | - | - | G1 | - |
| 403 | C | 244 | 1529704 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 14.02.11 | 1 | 21 | 1 | 3 | 3 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 16.11.10 | 23.08.11 | 12 | 1 | 05.08.11 | 2 | - | - | - | - | - |
| 404 | C | 124 | 1492423 | 1 | 1 | 1 | 1 | 1 | | 1 | 1 | 1 | 1 | 1 | 6.5 | 10.01.11 | 1 | 21 | 1 | 3 | 3 | 1 | - | 1 | 1 | 2 | 1 | 1 | 0 | 17.09.10 | 24.06.11 | 16 | 1 | 20.06.11 | 2 | | | | G1 | - |
| 405 | P | 91 | 1442440 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 10.01.11 | 1 | 27 | 1 | 3 | 3 | 1 | - | 1 | 1 | 3 | 1 | 1 | 1 | 30.09.10 | 07.07.11 | 15 | 1 | 31.07.11 | 2 | - | - | - | G1 | - |
| 406 | C | 162 | 1458799 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 03.01.11 | 1 | 19 | 1 | 3 | 3 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 23.09.10 | 30.06.11 | 14 | 1 | 22.06.11 | 2 | - | - | - | - | - |
| 407 | P | 150 | 1480056 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 30.12.10 | 1 | 20 | 1 | 3 | 2 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 30.09.10 | 07.07.11 | 18 | 1 | 06.07.11 | 2 | - | - | - | - | - |
| 408 | C | 263 | 1461360 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 09.12.10 | 1 | 21 | 2 | 2 | 3 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 03.09.10 | 10.06.11 | 13 | 1 | 19.06.11 | 2 | - | - | - | - | - |
| 409 | P | 218 | 1456284 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 03.12.10 | 1 | 28 | 1 | 2 | 3 | 1 | - | 1 | 1 | 2 | 1 | 1 | 0 | 09.10.10 | 17.07.11 | 12 | 1 | 15.07.11 | 2 | - | - | - | - | G1 |
| 412 | C | 152 | 1503496 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 20.01.11 | 1 | 21 | 1 | 2 | 3 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 22.10.10 | 29.07.11 | 12 | 1 | 03.08.11 | 2 | - | - | - | - | - |
| 413 | P | 185 | 1281974 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 08.02.11 | 1 | 30 | 1 | 2 | 2 | 1 | - | 1 | 1 | 3 | 2 | 2 | 0 | 10.11.10 | 17.08.11 | 14 | 1 | 21.07.11 | 2 | - | - | - | - | G1, G2 |
| 414 | C | 194 | 1515728 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 01.02.11 | 1 | 22 | 2 | 3 | 2 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 29.09.10 | 06.07.11 | 18 | 1 | 02.07.11 | 2 | - | - | - | - | - |
| 415 | P | 193 | 1493995 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 22.02.11 | 1 | 19 | 1 | 3 | 3 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 12.11.10 | 19.08.11 | 14 | 1 | 20.08.11 | 2 | - | - | - | - | - |
| 416 | C | 101 | 1459509 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 25.01.11 | 1 | 27 | 1 | 3 | 3 | 1 | - | 1 | 1 | 2 | 1 | 1 | 0 | 24.10.10 | 02.08.11 | 13 | 1 | 14.08.11 | 2 | - | - | - | G1 | - |
| 418 | P | 235 | 1515680 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 01.03.11 | 1 | 20 | 1 | 3 | 3 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 20.11.10 | 27.08.11 | 14 | 1 | 24.08.11 | 2 | - | - | - | - | - |
| 419 | P | 173 | 1452885 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 30.11.10 | 1 | 24 | 1 | 3 | 2 | 1 | - | 1 | 1 | 2 | 1 | 1 | 0 | 25.08.10 | 01.06.11 | 13 | 1 | 21.07.11 | 2 | - | - | - | G1 | - |
| 420 | P | 199 | 1540687 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 23.02.11 | 1 | 21 | 1 | 2 | 3 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 25.10.10 | 01.08.11 | 17 | 1 | 01.08.11 | 2 | - | - | - | - | - |
| 421 | P | 202 | 1495060 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 12.01.11 | 1 | 21 | 1 | 2 | 3 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 06.10.10 | 13.07.11 | 12 | 1 | 25.07.11 | 2 | - | - | - | - | - |
| 422 | C | 189 | 1541292 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 23.02.11 | 1 | 18 | 1 | 2 | 3 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 02.11.10 | 09.08.11 | 16 | 1 | 09.08.11 | 2 | - | - | - | - | - |
| 423 | C | 207 | 1501820 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 19.01.11 | 1 | 26 | 1 | 2 | 3 | 1 | - | 1 | 1 | 4 | 1 | 1 | 2 | 26.10.10 | 02.08.11 | 12 | 1 | 02.08.11 | 2 | - | - | - | G1, G2,G3 | * |
| 424 | P | 200 | 1487553 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 05.01.11 | 1 | 23 | 1 | 2 | 3 | 1 | - | 1 | 1 | 2 | 1 | 1 | 0 | 04.09.10 | 11.06.11 | 17 | 1 | 10.06.11 | 2 | - | - | - | G1 | - |
| 425 | C | 164 | 1487295 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 23.02.11 | 1 | 26 | 1 | 2 | 3 | 1 | - | 1 | 1 | 2 | 1 | 1 | 0 | 19.11.10 | 26.08.11 | 12 | 1 | 04.09.11 | 2 | - | - | - | G1 | - |
| 438 | C | 159 | 93957 | 1 | 1 | 1 | 1 | 1 | | 1 | 1 | 1 | 1 | 1 | 5.0 | 08.02.11 | 1 | 25 | 1 | 2 | 3 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 28.11.10 | 04.08.11 | 14 | 1 | 12.08.11 | 2 | - | - | - | - | - |
| 451 | P | 66 | 939476 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 02.03.11 | 1 | 26 | 2 | 4 | 3 | 1 | - | 1 | 1 | 2 | 1 | 1 | 0 | 01.11.10 | 08.08.11 | 17 | 1 | 01.08.11 | 2 | - | - | - | G1 | - |
| 460 | P | 51 | 1507287 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 24.01.11 | 1 | 24 | 2 | 2 | 3 | 1 | - | 1 | 1 | 2 | 1 | 1 | 0 | 26.10.10 | 02.08.11 | 12 | 1 | 09.08.11 | 2 | - | - | - | G1 | - |
| 461 | P | 223 | 96513 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 15.11.10 | 1 | 27 | 1 | 6 | 3 | 1 | - | 1 | 1 | 2 | 0 | 0 | 1 | 25.08.10 | 01.05.11 | 11 | 1 | 10.05.11 | 2 | - | - | - | G1 | 3 mn A |
| 462 | P | 102 | 99411 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 06.02.11 | 1 | 24 | 1 | 2 | 3 | 1 | - | 1 | 1 | 2 | 1 | 1 | 0 | 30.12.10 | 06.09.11 | 12 | 1 | 05.09.11 | 2 | - | - | - | G1 | - |
| 468 | C | 94 | 1516363 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 02.03.11 | 1 | 33 | 1 | 3 | 3 | 1 | - | 1 | 1 | 2 | 1 | 1 | 0 | 24.10.10 | 31.07.11 | 14 | 1 | 07.08.11 | 2 | - | - | - | G1 | - |
| 469 | P | 183 | 92995 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 30.11.10 | 1 | 19 | 1 | 4 | 1 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 27.08.10 | 03.07.11 | 14 | 1 | 02.07.11 | 2 | - | - | - | - | - |
| 470 | C | 98 | 101865 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 30.12.10 | 1 | 24 | 1 | 2 | 3 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 13.09.10 | 20.06.11 | 16 | 1 | 19.06.11 | 2 | - | - | - | - | - |
| 474 | C | 86 | 95977 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.5 | 26.01.11 | 1 | 28 | 1 | 2 | 3 | 1 | - | 1 | 1 | 2 | 1 | 1 | 0 | 28.10.11 | 04.07.11 | 12 | 1 | 06.07.11 | 2 | - | - | - | G1 | - |
| 475 | C | 45 | 822011 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 02.02.11 | 1 | 21 | 1 | 2 | 3 | 1 | - | 1 | 1 | 2 | 1 | 1 | 0 | 25.10.10 | 02.08.11 | 15 | 1 | 31.07.11 | 2 | - | - | - | G1 | - |
| 477 | P | 65 | 1236180 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 08.02.11 | 1 | 26 | 1 | 3 | 3 | 1 | - | 1 | 1 | 3 | 1 | 1 | 1 | 14.10.10 | 21.07.11 | 16 | 1 | 26.07.11 | 2 | - | - | - | G1,G2 | A |
| 484 | P | 7 | 98626 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 06.12.10 | 1 | 19 | 1 | 4 | 1 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 30.08.10 | 28.03.11 | 14 | 1 | 04.04.11 | 2 | - | - | - | - | - |
| 486 | P | 58 | 1472188 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 08.02.11 | 1 | 19 | 1 | 3 | 3 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 25.10.10 | 01.08.11 | 15 | 1 | 02.08.11 | 2 | - | - | - | - | - |
| 488 | P | 122 | 1485835 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 08.02.11 | 1 | 28 | 2 | 3 | 3 | 1 | - | 1 | 1 | 4 | 3 | 1 | 0 | 22.10.10 | 29.07.11 | 15 | 1 | 29.07.11 | 1 | 1 | 2 | 1 | G1,G2,G3 | |
| 496 | P | 167 | 1564745 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 15.03.11 | 1 | 23 | 3 | 4 | 3 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 11.11.10 | 18.08.11 | 17 | 1 | 16.08.11 | 2 | - | - | - | - | - |
| 498 | C | 24 | 96863 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.0 | 24.01.11 | 1 | 24 | 2 | 2 | 3 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 17.10.10 | 24.06.11 | 14 | 1 | 20.06.11 | 2 | - | - | - | - | - |

## ANNEXURE III - MASTER CHART

| Serial Number | Group | Clindamycin No. | Identification Number | Previous pregnancy outcome | | | | | | | Examination | | | | | | | | | | | Hb (gm%) | Randomization | Medication | Course | Reason | Side effects | Empty packs | Pregnancy outcome | Causes | Mode of delivery | Indication | Birth information | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | | | | | Blood pressure | | System | | | | | | | | | | | | | | | | | | | | |
| | | | | Outcome | Newborn weight | Sex | Alive | Current age (Years) | Maternal complication | Outcome of baby | Height (Cms) | Weight (Kgs) | BMI (Kg/m$^2$) | PR (/Min) | SBP (mm Hg) | DBP (mm Hg) | CVS | RS | Uterus | Fundal height (Wks) | Eligibility | | | | | | | | | | | | Date | Sex | Gestational age (wks) | Weight (Kg) |
| 400 | P | 144 | 1561786 | 4,4 | 2,2 | 1,1 | 2,1 | 2.5,1.5 | 2,6 | FSB,1 | 152 | 42 | 18.18 | 80 | 116 | 74 | 1 | 1 | 1 | 16 | 1 | 11.50 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 07.07.11 | M | 39.3 | 2.5 |
| 401 | P | 181 | 1538586 | 1 | 2 | 2 | 1 | - | 6 | 1 | 146 | 95 | 44.57 | 80 | 110 | 76 | 1 | 1 | 1 | 18 | 1 | 10.50 | 1 | 1 | 1 | - | - | 1 | N | - | LSCS | POST DAT | 20.06.11 | F | 39.3 | 2.6 |
| 403 | C | 244 | 1529704 | - | - | - | - | - | - | - | 156 | 44 | 18.08 | 80 | 126 | 84 | 1 | 1 | 1 | 12 | 1 | 9.20 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 30.07.11 | F | 39.1 | 3.0 |
| 404 | C | 124 | 1492423 | 1 | 2 | 2 | 1 | 1.5 | 6 | 1 | 147 | 40 | 18.51 | 80 | 116 | 74 | 1 | 1 | 1 | 16 | 1 | 10.00 | 1 | 1 | 1 | - | - | 1 | N | - | V | HOME DEL ? | 14.06.11 | M | 38.4 | 3.1 |
| 405 | P | 91 | 1442440 | 1 | 2 | 2 | 1 | 1.5 | 6 | 1 | 158 | 58 | 23.23 | 80 | 126 | 70 | 1 | 1 | 1 | 16 | 1 | 8.00 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 28.07.11 | M | 39.4 | 3.1 |
| 406 | C | 162 | 1458799 | - | - | - | - | - | - | - | 160 | 50 | 19.53 | 80 | 126 | 84 | 1 | 1 | 1 | 12 | 1 | 11.00 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 02.05.11 | M | 31.4 | 1.8 |
| 407 | P | 150 | 1480056 | - | - | - | - | - | - | - | 154 | 54 | 22.77 | 80 | 126 | 74 | 1 | 1 | 1 | 18 | 1 | 11.50 | 1 | 1 | 1 | - | - | 1 | N | - | V | PPROM | 01.07.11 | F | 39.0 | 2.8 |
| 408 | C | 263 | 1461360 | - | - | - | - | - | - | - | 146 | 35 | 16.42 | 80 | 110 | 74 | 1 | 1 | 1 | 14 | 1 | 12.20 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 08.06.11 | F | 39.5 | 2.9 |
| 409 | P | 218 | 1456284 | 4 | 2 | 2 | 1 | 4 | 6 | 1 | 150 | 52 | 23.11 | 80 | 130 | 80 | 1 | 1 | 1 | 12 | 1 | 10.00 | 1 | 1 | 1 | - | - | 1 | N | - | LSCS | Br | 14.07.11 | M | 39.4 | 3.3 |
| 412 | C | 152 | 1503496 | - | - | - | - | - | - | - | 156 | 40 | 16.44 | 80 | 126 | 86 | 1 | 1 | 1 | 12 | 1 | 10.00 | 1 | 1 | 1 | - | - | 1 | N | - | V | UNCONT HTN | 21.07.11 | M | 38.6 | 2.3 |
| 413 | P | 185 | 1281974 | 1,1 | 2,2 | 2,2 | 1,1 | 9,2 | 6,6 | 1,3 | 144 | 42 | 20.25 | 86 | 120 | 80 | 1 | 1 | 1 | 14 | 1 | 12.20 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 19.08.11 | M | 40.2 | 3.3 |
| 414 | C | 194 | 1515728 | - | - | - | - | - | - | - | 160 | 57 | 22.27 | 76 | 126 | 76 | 1 | 1 | 1 | 18 | 1 | 10.00 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 30.06.11 | M | 39.1 | 2.8 |
| 415 | P | 193 | 1493995 | - | - | - | - | - | - | - | 150 | 46 | 20.44 | 80 | 110 | 70 | 1 | 1 | 1 | 14 | 1 | 10.50 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 04.08.11 | F | 37.6 | 3.0 |
| 416 | C | 101 | 1459509 | - | - | - | - | 5 | - | - | 152 | 42 | 18.18 | 80 | 126 | 84 | 1 | 1 | 1 | 12 | 1 | 12.00 | 1 | 1 | 1 | - | - | 1 | N | - | LSCS | Br | 08.08.11 | F | 40.6 | 2.1 |
| 418 | P | 235 | 1515680 | - | - | - | - | - | - | - | 148 | 50 | 22.83 | 92 | 126 | 84 | 1 | 1 | 1 | 14 | 1 | 12.00 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 24.08.11 | M | 39.3 | 2.4 |
| 419 | P | 173 | 1452885 | 1 | IUD | 2 | 2 | 1 | 6 | IUD | 146 | 50 | 23.46 | 84 | 120 | 84 | 1 | 1 | 1 | 12 | 1 | 9.50 | 1 | 1 | 1 | - | - | 1 | N | - | V | PPROM | 26.04.11 | F | 35.0 | 1.3 |
| 420 | P | 199 | 1540687 | - | - | - | - | - | - | - | 145 | 39 | 18.55 | 80 | 124 | 86 | 1 | 1 | 1 | 16 | 1 | 10.00 | 1 | 1 | 1 | - | - | 1 | N | - | LSCS | Br | 07.08.11 | M | 41.1 | 2.8 |
| 421 | P | 202 | 1495060 | - | - | - | - | - | - | - | 142 | 46 | 22.81 | 84 | 128 | 76 | 1 | 1 | 1 | 12 | 1 | 9.50 | 1 | 1 | 1 | - | - | 1 | N | - | LSCS | SEV PIH | 03.07.11 | M | 40.5 | 2.3 |
| 422 | C | 189 | 1541292 | - | - | - | - | - | - | - | 150 | 44 | 19.56 | 80 | 126 | 86 | 1 | 1 | 1 | 16 | 1 | 12.00 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 16.08.11 | M | 41.0 | 3.5 |
| 423 | C | 207 | 1501820 | 4 | 2 | 1 | 1 | 5 | 6 | 1 | 146 | 42 | 19.70 | 80 | 110 | 74 | 1 | 1 | 1 | 12 | 1 | 11.50 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 30.07.11 | F | 39.4 | 3.0 |
| 424 | P | 200 | 1487553 | 1 | 2 | 2 | 1 | 2 | 6 | 1 | 150 | 40 | 17.78 | 80 | 120 | 86 | 1 | 1 | 1 | 16 | 1 | 9.00 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 16.06.11 | M | 40.5 | 3.1 |
| 425 | C | 164 | 1487295 | 4 | 1 | 2 | 1 | 2 | 6 | 1 | 150 | 58 | 25.78 | 84 | 120 | 86 | 1 | 1 | 1 | 12 | 1 | 10.00 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 13.08.11 | F | 38.0 | 3.2 |
| 438 | C | 159 | 93957 | - | - | - | - | - | - | - | 156 | 48 | 19.72 | 80 | 100 | 70 | 1 | 1 | 1 | 14 | 1 | 9.20 | 1 | 1 | 1 | - | - | 1 | N | - | LSCS | FT DIST | 06.08.11 | M | 40.2 | 2.5 |
| 451 | P | 66 | 939476 | 1 | 2 | 1 | 1 | 3 | 6 | 1 | 155 | 39 | 16.23 | 82 | 110 | 70 | 1 | 1 | 1 | 16 | 1 | 11.00 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 07.08.11 | F | 39.3 | 2.8 |
| 460 | P | 51 | 1507287 | 1 | 2 | 2 | 1 | 2 | 6 | 1 | 152 | 46 | 19.91 | 76 | 100 | 60 | 1 | 1 | 1 | 12 | 1 | 11.00 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 22.07.11 | F | 38.3 | 2.2 |
| 461 | P | 223 | 96513 | 5 | - | - | - | - | 6 | - | 140 | 38 | 19.39 | 92 | 110 | 70 | 1 | 1 | 1 | 12 | 1 | 11.60 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 19.12.10 | - | 16.4 | 0.5 |
| 462 | P | 102 | 99411 | 1 | 2 | 2 | 1 | 2.5 | 6 | 1 | 151 | 44 | 19.30 | 76 | 126 | 84 | 1 | 1 | 1 | 12 | 1 | 13.40 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 31.08.11 | F | 39.0 | 3.0 |
| 468 | C | 94 | 1516363 | 4 | 2 | 2 | 1 | 6 | 6 | 1 | 160 | 51 | 19.92 | 80 | 120 | 76 | 1 | 1 | 1 | 16 | 1 | 12.00 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 30.07.11 | M | 39.6 | 2.5 |
| 469 | P | 183 | 92995 | - | - | - | - | - | - | - | 150 | 40 | 17.78 | 82 | 110 | 70 | 1 | 1 | 1 | 14 | 1 | 10.20 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 14.05.11 | F | 31.2 | 2.0 |
| 470 | C | 98 | 101865 | - | - | - | - | - | - | - | 150 | 52 | 23.11 | 80 | 110 | 70 | 1 | 1 | 1 | 16 | 1 | 9.20 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 11.06.11 | M | 38.5 | 2.9 |
| 474 | C | 86 | 95977 | 1 | 2 | 2 | 1 | 1.5 | 6 | 6 | 152 | 48 | 20.78 | 80 | 110 | 70 | 1 | 1 | 1 | 12 | 1 | 11.60 | 1 | 1 | 1 | - | - | 1 | N | - | V | OLIG | 01.06.11 | F | 34.4 | 3.0 |
| 475 | C | 45 | 822011 | 1 | 2 | 2 | 1 | 2 | 6 | 1 | 152 | 42 | 18.18 | 80 | 120 | 70 | 1 | 1 | 1 | 16 | 1 | 10.50 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 30.07.11 | F | 39.4 | 2.9 |
| 477 | P | 65 | 1236180 | 1 | 2 | 1 | 1 | 2.5 | 6 | 1 | 150 | 39 | 17.33 | 72 | 122 | 72 | 1 | 1 | 1 | 16 | 1 | 10.00 | 1 | 1 | 1 | - | - | 1 | N | - | LSCS | PRECIOUS PREG | 21.07.11 | F | 40.0 | 3.0 |
| 484 | P | 7 | 98626 | - | - | - | - | - | - | - | 149 | 44 | 19.82 | 84 | 120 | 86 | 1 | 1 | 1 | 14 | 1 | 13.00 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 02.04.11 | M | 40.5 | 3.0 |
| 486 | P | 58 | 1472188 | - | - | - | - | - | - | - | 161 | 46 | 17.75 | 80 | 106 | 78 | 1 | 1 | 1 | 16 | 1 | 10.00 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 05.08.11 | M | 40.4 | 3.2 |
| 488 | P | 122 | 1485835 | 1,2,1 | 2,1,2 | 2,2,1 | 2,2,1 | 10,7,5 | 6,6,6 | FSB, I* * | 152 | 36 | 15.58 | 80 | 100 | 68 | 1 | 1 | 1 | 16 | 1 | 9.00 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 03.08.11 | M | 40.5 | 2.6 |
| 496 | P | 167 | 1564745 | - | - | - | - | - | - | - | 146 | 44 | 20.64 | 74 | 120 | 70 | 1 | 1 | 1 | 16 | 1 | 11.00 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 16.08.11 | F | 39.5 | 2.5 |
| 498 | C | 24 | 96863 | - | - | - | - | - | - | - | 146 | 58 | 27.21 | 80 | 110 | 60 | 1 | 1 | 1 | 14 | 1 | 12.00 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 21.06.11 | M | 39.4 | 2.9 |

## ANNEXURE III - MASTER CHART

| Serial Number | Group | Clindamycin No. | Identification Number | Screening | | | | | | | | | | | | Final result | | Age (Years) | Occupation | Education | Socio economic status | Vaginal Discharge | Smelling | Pruiritis | Menstrual cycle | Gravida | Para | Living | Abortion | LMP | EDD | POG | | Acc. To USG EDD | Previous pregnancies | | | | Previous pregnancy outcome | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | GA 13 to 16 ±1 Week | Single pregnancy | H/o antibiotic use within 14 days | Known fata anomaly | Maternal medical complications | Complication | Cervical cerclage | Fever | Willingness for consent | Consent | Vaginal pH ≥ 5 | Vaginal pH | Date | Result | | | | | | | | | | | | | | | Estimated | Corr with scan | | Preterm | No of births | Type of labour | Type of delivery | Year | Duration |
| 499 | C | 113 | 600510 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.5 | 02.02.11 | 1 | 29 | 1 | 2 | 3 | 1 | - | 1 | 1 | 2 | 1 | 1 | 0 | 20.10.10 | 27.07.11 | 13 | 1 | 08.08.11 | 2 | - | - | - | G1 | - |
| 500 | P | 112 | 1500624 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 18.01.11 | 1 | 21 | 2 | 3 | 3 | 1 | - | 1 | 1 | 3 | 1 | 0 | 1 | 25.10.10 | 02.08.11 | 12 | 1 | 09.08.11 | 2 | - | - | - | G1,G2 | A |
| 501 | P | 4 | 105452 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 12.04.11 | 1 | 20 | 1 | 3 | 3 | 1 | - | 1 | 1 | 1 | 0 | 0 | 0 | 31.12.10 | 06.09.11 | 14 | 1 | 09.09.11 | 2 | - | - | - | - | - |
| 506 | C | 178 | 102706 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 5.0 | 14.12.10 | 1 | 28 | 1 | 3 | 2 | 1 | - | 1 | 1 | 2 | 1 | 1 | 0 | 10.09.10 | 17.06.11 | 13 | 1 | 11.06.11 | 2 | - | - | - | - | G1 |
| 509 | C | 52 | 100719 | 1 | 1 | 1 | 1 | 1 | - | 1 | 1 | 1 | 1 | 1 | 6.0 | 02.02.11 | 1 | 34 | 1 | 2 | 3 | 1 | - | 1 | 1 | 6 | 2 | 2 | 3 | 25.10.10 | 01.07.11 | 14 | 1 | 30.06.11 | 2 | - | - | - | G1, A1, A2, G2, A3 | - |

## ANNEXURE III - MASTER CHART

| Serial Number | Group | Clindamycin No. | Identification Number | Previous pregnancy outcome | | | | | | | Examination | | | | | | | | | | | Hb (gm%) | Randomization | Medication | Course | Reason | Side effects | Empty packs | Pregnancy outcome | Causes | Mode of delivery | Indication | Birth information | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | | | | | Blood pressure | | System | | | | | | | | | | | | | | | | | | | |
| | | | | Outcome | Newborn weight | Sex | Alive | Current age (Years) | Maternal complication | Outcome of baby | Height (Cms) | Weight (Kgs) | BMI (Kg/m$^2$) | PR (/Min) | SBP (mm Hg) | DBP (mm Hg) | CVS | RS | Uterus | Fundal height (Wks) | Eligibility | | | | | | | | | | | | Date | Sex | Gestational age (wks) | Weight (Kg) |
| 499 | C | 113 | 600510 | 4 | 2 | 2 | 1 | 2 | 6 | 1 | 148 | 39 | 17.80 | 80 | 126 | 80 | 1 | 1 | 1 | 12 | 1 | 13.00 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 01.08.11 | F | 39.0 | 3.2 |
| 500 | P | 112 | 1500624 | 4 | 2 | 2 | 2 | 2 | 6 | A | 157 | 50 | 20.28 | 84 | 130 | 80 | 1 | 1 | 1 | 12 | 1 | 10.00 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 02.06.11 | F | 32.0 | 1.0 |
| 501 | P | 4 | 105452 | - | - | - | - | - | - | - | 158 | 74 | 29.64 | 80 | 120 | 84 | 1 | 1 | 1 | 14 | 1 | 8.20 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 01.09.11 | M | 39.5 | 1.6 |
| 506 | C | 178 | 102706 | 4 | 2 | 1 | 1 | 3 | 6 | 1 | 146 | 50 | 23.46 | 64 | 130 | 84 | 1 | 1 | 1 | 12 | 1 | 11.40 | 1 | 1 | 1 | - | - | 1 | N | - | N | - | 15.06.11 | M | 39.5 | 3.0 |
| 509 | C | 52 | 100719 | - | - | - | - | - | - | - | 156 | 50 | 20.55 | 84 | 120 | 86 | 1 | 1 | 1 | 14 | 1 | 8.20 | 1 | 1 | 1 | - | - | 1 | N | - | LSCS | FT DIST | 04.07.11 | F | 40.3 | 3.2 |

# ANNEXURE III – KEY TO MASTER CHART

| | | |
|---|---|---|
| 1 | - | Yes |
| 2 | - | No |
| A | - | Abortion |
| Abr | - | Abruption |
| Acc | - | According |
| Anen | - | Anencephaly |
| BMI | - | Body mass index |
| Br | - | Breech |
| C | - | Clindamycin group |
| Cms | - | Centimeters |
| Corr | - | Correlation |
| CVS | - | Cardiovascular system |
| DBP | - | Diastolic blood pressure |
| ECL | - | Eclampsia |

Education

| | | |
|---|---|---|
| 1 | - | Illiterate |
| 2 | - | Read |
| 3 | - | Write |
| 4 | - | Primary |
| 5 | - | Secondary |
| 6 | - | Graduate |
| 7 | - | Post graduate |

| | | |
|---|---|---|
| EPP | - | Expected date of pregnancy |
| Est Pt | - | Established preterm |
| F | - | Female |
| FBS | - | Fresh macerated stillbirth |
| Final result | - | |
| 1 | - | Eligible Participating |
| 2 | - | Eligible Refusal |
| 3 | - | Ineligible |
| FL IND | - | Failed induction |
| FT DST | - | Fetal distress |
| G | - | Gravida |
| GA | - | Gestational age |
| gm | - | Grams |
| H/o | - | History of |
| HOM DEL | - | Home delivery |
| IUD | - | Intrauterine death |
| IUGR | - | Intrauterine growth retardation |
| Kgs | - | Kilograms |
| LMP | - | Last menstrual period |
| LSCS | - | Lower segment caesarean section |
| M | - | Male |
| m | - | Meter |
| Matern Req | - | Maternal request |
| Min | - | Minute |

| | | |
|---|---|---|
| Missed abort | - | Missed abortion |
| mm Hg | - | Millimeters of mercury |
| mn | - | Months |
| Mode of delivery | | |
| N | - | Normal |
| V | - | Ventouse |
| LSCS | - | Lower segment caesarean section |
| No. | - | Number |
| Not will VBAC | - | Not willing for vaginal birth after caesarean |
| NPL | - | Non progress of labour |
| Occupation | | |
| 1 | - | HW |
| 2 | - | Working |
| 3 | - | Laborer |
| 4 | - | Professional |
| OLIG | - | Oligohydroamnios |
| P | - | Placebo group |
| pH | - | Power of hydrogen |
| POG | - | Period of gestation |
| Post dat | - | Post datism |
| PR | - | Pulse rate |
| Prev | - | Previous |
| RS | - | Respiratory system |
| SBP | - | Systolic blood pressure |

Socio economic status

1 - White

2 - Green

3 - Yellow

4 - Red

5 - Pan (income Tax)

USG - Ultrasound

Vaginal discharge smelling

1 - Foul smelling

2 - Non foul smelling.

Wks - Weeks