Study Protocol

Title:

Comparative Analysis of Oral Iron with Injectable Ferric Carboxymaltose for treatment of Postpartum Iron Deficiency anaemia

Date: 23 February 2024

PRINCIPAL INVESTIGATOR: DR. SHREYA MAHAJAN

POSTGRADUATE STUDENT DEPARTMENT OF OBSTETRICS AND GYNAECOLOGY

Institution: ESI PGIMSR & ESI Model Hospital, Basaidarapur New Delhi

IEC Approval Number: IEC/2024031

COMPARATIVE ANALYSIS OF ORAL IRON WITH INJECTABLE FERRIC CARBOXYMALTOSE FOR TREATMENT OF POST PARTUM IRON DEFICINECY ANAEMIA

Protocol of Thesis submitted to Guru Gobind Singh Indraprastha University Delhi towards the Partial Fulfilment of the Requirement for the Degree of Master of Surgery (Obstetrics & Gynaecology)

(Batch: 2023-2026)

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Supervisor:

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ESI-PGIMSR Basaidarapur, New Delhi.

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DECLARATION

I wish to undertake a thesis project entitled "COMPARATIVE ANALYSIS OF ORAL IRON WITH INJECTABLE FERRIC CARBOXYMALTOSE FOR TREATMENT OF POST PARTUM IRON DEFICIENCY ANAEMIA" to fulfil the essential requirement for the award of degree of Master of Surgery (Obstetrics and Gynaecology) from Guru Gobind Singh Indraprastha University, New Delhi. I hereby declare that the thesis protocol does not violate the copyright act in any way, is free of plagiarism and that the "questionnaires" or "scores" being used are copyright - free or that the necessary permission has been obtained from the copyright holders. The work does not include any diagrams, figures, tables and flowcharts which are copied from a journal or book or infringe copyright.

Signature of candidate

Dr Shreya Mahajan

CERTIFICATE

This is to certify that the study "**COMPARATIVE ANALYSIS OF ORAL IRON WITH INJECTABLE FERRIC CARBOXYMALTOSE FOR TREATMENT OF POST PARTUM IRON DEFICIENCY ANAEMIA**" shall be carried out under the guidance and supervision of Dr. Disha Andhiwal Rajput in the department of Obstetrics and Gynaecology at ESI- PGIMSR, Basaidarapur, New Delhi

Candidate: Dr. Shreya Mahajan
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Supervisor: Dr. Disha Andhiwal Rajput
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ESI Hospital, Basaidarapur, New Delhi.

Signature

CERTIFICATE

This is to certify that the work entitled, "**Comparative Analysis of Oral Iron with Injectable Ferric Carboxymaltose for Treatment of Postpartum Iron Deficiency Anaemia**" shall be carried out in the Department of Obstetrics and Gynaecology, ESIC, PGIMSR Model Hospital Basaidarapur, New Delhi. It is certified that the study is feasible in the given time frame and that the institution has machinery and equipment and other essential prerequisites for conducting the study and that the study sample size has been calculated on the basis of relatable statistical formula and that it satisfies the requirements of study design and the proposed statistical analysis. It is certified that the thesis plan is not a repetition of a similar study undertaken in the previous five years in the university and that the study is not based on a retrospective collection or analyses of data from old patient case records and that it does not employ any "off label drug trials." We undertake that the participants enrolled in the thesis project will not have to bear any financial burden on account of the investigation, devices, implants or drugs employed as part of the study, and that the study does not require us to partake of any obligation or any favour from a pharmaceutical company, device manufacturer or medical supplier.

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Institutional Review Board Certificate
(Scientific Committee)

The Institutional Review Board / Scientific Committee of ESI-PGIMSR, Basaidarapur has reviewed and discussed the research protocols of **Dr. Shreya Mahajan,** PG-student, Department of OBG, titled "Comparative analysis between oral iron and ferric carboxymaltose injection for the treatment of post partum iron deficiency anaemia" on 30.01.2024 under the supervision of Dr. Disha Andhiwal Rajput, Professor, Department of OBG.

The Institutional Review Board / Scientific Committee duly reviewed the thesis protocol in line with the formally ratified 2019 regulations of the USM & PMHS, Guru Gobind Singh Indraprastha University, and found the Introduction; Review of Literature; Lacunae in existing knowledge; Research question and Hypothesis; Aims and objectives; Material and Methods; Statistical method; References; and Appendices to be suitably drawn and based on sound scientific and ethical foundation.

The Institutional Review Board / Scientific Committee confirms that the supervisor and co-supervisors of the study meet the formally ratified 2019 regulations of the USM & PMHS, Guru Gobind Singh Indraprastha University, and that neither the supervisor nor co-supervisors are a part of thesis projects more than that permitted to them.

The Institutional Review Board / Scientific Committee meeting was chaired by Dr. M. Ganesh, and the following members of the committee were present during the meeting:

01. Dr. Prasad CGS
02. Dr. Jayati Chakraborty
03. Dr. Gaurav patel
04. Dr. Jyoti Bagla
05. Dr. Preetham S
06. Dr. Rajesh Chetiwal
07. Dr. Sonia Khattar
08. Dr. U C Ojha
09. Dr. Sarika Arora

The Institutional Review Board / Scientific Committee approved the study to be conducted in the present form at ESI-PGIMSR, ESI- Hospital, Basaidarapur, New Delhi.

Chairperson/Dean,
Institutional Review Board / Scientific Committee
डॉ. एम. गणेश/Dr. M. Ganesh
अधिष्ठाता/Dean
क.रा.बी. अस्पताल सह पीजीआईएमएसआर/ESI Hospital cum PGIMSR
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DM(A)H-19/14/17/IEC/2012-PGIMSR(part-II) Dated: 23.02.2024

DECISION LETTER

The IEC, ESI-PGIMSR, Basaidarapur, New Delhi in its meeting held on **08.02.2024** has reviewed and discussed thesis protocol with Reg. no. ESIPGIMSR-**IEC/2024031**titled: **"COMPARATIVE ANALYSIS OF ORAL IRON WITH INJECTABLE FERRIC CARBOXYMALTOSE FOR TREATMENT OF POST PARTUM IRON DEFICIENCY ANAEMIA"** From**Dr. SHREYA MAHAJAN**,Department of OBG, ESI PGIMSR, Basaidarapur, New Delhi, under the supervision of **Dr. Disha Andhiwal Rajput.**

The members presented a quorum as per IEC, ESI-PGIMSR, SOP. After due consideration, the Chairman IEC has decided to **approve** the above titled thesis protocol.

The Investigator is requested to submit the progress report after 3/6 months (depending on the duration of the project) to IEC for review. The final outcome / findings need to be submitted to IEC after completion of the project / study / research. Any change, modification or deviation in the protocol or any adverse events must be informed to the IEC immediately. Any protocol modification or amendment must receive fresh IEC approval. In the event of any deviation from the above or non compliance of conditions, the ethical clearance will deem to have been withdrawn. Investigator must conduct the study as per Good Clinical Practice guidelines.

Sonia Khattar 23/02/24

Dr. Sonia Khattar,
सदस्य सचिव आई.ई.सी. / Member Secretary of IEC
Member Secretary- IEC ई.रा.बी.मॉडल अस्पताल सह पीजीआईएमएसआर
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INTRODUCTION

Anaemia is the most common medical disorder amongst pregnant and lactating women in developing countries like India, with a prevalence of 50-80%. It contributes to high maternal morbidity and mortality. Postpartum anaemia has been defined as haemoglobin (Hb) less than 11 g/dl in early postpartum period [1]. Many factors contribute to this high prevalence such as poor dietary intake, predominantly vegetarian diet, chronic blood loss due to infections such as malaria, hook worm infestation, repeated pregnancies at short interval etc[1]. Despite a functional National Anaemia Control Programme (NACP) in our country for more than 40 years, the problem largely remains unsolved.

Definitive treatment of postpartum iron deficiency anaemia (PPIDA) is iron therapy by oral or parenteral route. Oral therapy is the treatment of choice but its use is limited due to intolerability and poor compliance [2,3]. After oral iron therapy, Hb starts rising from third week but replenishment of iron stores may take up to 3 months. Parenteral iron therapy ensures good compliance, rapid correction of anaemia and replenishment of iron stores. Use of first-generation intramuscular iron dextran has been limited by side effects such as life-threatening anaphylaxis and delayed hypersensitivity reactions (arthralgia, myalgia, fever, local site burning etc). Second generation IV iron like Iron sucrose and ferric gluconate have lower incidence of side effects but need multiple doses and prolonged infusion time[4]. There is need for newer, safer and preferably single dose therapy.

Ferric carboxymaltose (FCM) injection is a novel third generation intravenous iron agent, approved by Drug Controller General of India in 2011. FCM comprises a macromolecular iron-hydroxide complex of polynuclear iron (III) hydroxide tightly bound in a carbohydrate shell. This design allows for controlled delivery and minimal risk of release of large amount of ionic

iron in the serum. This avoids the risk of acute toxicity associated with many other iron compounds but at the same time allowing large amount of iron to be delivered. There is a much wider therapeutic window. Efficacy and safety of FCM has been proved in many clinical trials done so far in patients of PPIDA [5,6], heavy uterine bleeding[7] and chronic kidney disease.

The present literature in PPIDA show consistent results regarding comparative efficacy of FCM injection and oral iron in increasing haemoglobin. FCM injection leads to haemoglobin rise along with replenishment of iron stores in much shorter time. Also, there is better tolerability with low risk of anaphylaxis and other adverse effects. A sub study on breast milk has been done showing it to be safe for infants also[8].FCM group showed better compliance due to less number of doses and fewer injection site problems.

FCM seems promising in the treatment of PPIDA. Most of the studies have been done outside India, however, there is need for data in Indian population.

REVIEW OF LITERATURE

FERRIC CARBOXYMALTOSE (FCM)

FCM injection is a novel third generation intravenous iron agent. It is stable at physiological pH and large amount of iron can be given at one time. Thus, it combines the positive characteristics of iron dextran and iron sucrose and stands near the ideal intravenous iron preparation. Moreover, total dose infusion is possible with lesser side effects.

CLINICAL TRIALS USING FCM IN POSTPARTUM IRON DEFICIENCYANEMIA (PPIDA)

Study by Yildiz et al (2021) involving 291 women with postpartum anaemia, six-week comparative trial found that 91.4% of women who received ferric carboxymaltose had higher haemoglobin concentrations compared to 66.7% of women who received oral ferrous sulphate [(9)].

Van Wyck et al 2007[10]conducted a multicentric open-label, phase 3, randomized controlled trial comparing FCM with oral iron in 352 postpartum anaemic women. They found that FCM injection is as effective as oral iron in achieving Hb rise of more than 2 g/dl and improvement of quality of life; that too at a much faster rate. Adherence rate to therapy was greater in FCM group (98%) than oral iron group (83%). Oral group patients reported gastrointestinal symptoms, while FCM group patients showed skin reactions such as mild pruritus, rash which were transient and subsided within 5-15minutes.

In a similar multicentric study by Breymann et al 2008[(8)] on 348 postnatal women spread over 20 centres in 3 countries in a 12-week study period, findings were almost same. Unlike previous study, there was not much difference in mean compliance (>90% for oral ferrous

sulphate and 100% for FCM injection). There was no statistically significant difference in mean haemoglobin rise in both the groups. However, there was significant increase in FCM group in serum ferritin ($p<0.001$) and transferrin saturation ($p<0.004$), but no change in red cell indices in both the groups. Overall side effect profile was similar. However, infections such as nasopharyngitis and respiratory tract infections were more common in FCM group than oral group (8.4% versus3.4%). Infusion site burning (2.2%) and infusion site pain (1.3%) were reported exclusively in FCM group. Two patients in FCM group reported severe adverse reactions i.e. increase in hepatic enzymes and hypersensitivity, but no case of anaphylactic shock was found. A sub-study on breast milk on 25 patients found increased iron level in breast milk in FCM group at 48 hr after the first dose, with no significant side effects.

Seid et al 2008 [(5)] conducted an RCT on 291 postpartum anaemic women and proposed superior efficacy of FCM injection over oral iron in correcting anaemia (91.4% versus 66.7%), in improving iron stores measured by serum ferritin (238 ng/ml versus 21 ng/ml; $p<0.001$). Mild to moderate adverse events such as nausea, urticaria, muscle cramps and headache were found in both the groups

In a retrospective cohort study, Pfenniger et al 2012[(6)] compared FCM with iron sucrose (IS) in 210 postpartum anaemic women. Both drugs were found to be safe with overall adverse effects of 5% in FCM versus 6% in IS group. Main symptom was burning and pain at injection site, less so in FCM group. Moreover, both FCM and IS were found to be equally effective in increasing Hb level.

In a comparative study of efficacy and safety of parenteral iron sucrose versus ferric carboxymaltose in treatment of postpartum iron deficiency anaemia by Ganesh N. Dakhale et al in 2022 [11] showed early, sustained and significant increase in the haemoglobin levels in both the groups. However, the difference was not significant between groups. However, on evaluation of replenishment of iron stores (serum ferritin) showed improvement in both the groups, however in FCM group the rise was found to be significant superior.

LACUNAE IN EXISTING KNOWLEGDE

There have been many studies conducted on Anaemia and its treatment but limited studies have been carried out in Indian population with regards to injectable Ferric Carboxymaltose and oral iron for post partum women with iron deficiency anaemia.

RESEARCH QUESTION

Is Ferric carboxymaltose injection safer and more effective than oral iron supplementation in the treatment of Post partum females with iron deficiency anaemia ?

HYPOTHESIS

Ferric carboxymaltose injection will demonstrate superior effectiveness and safety compared to oral iron supplementation in addressing postpartum iron deficiency anaemia.

AIMS AND OBJECTIVES

Aim

To compare the effectiveness and safety of ferric carboxymaltose injection with oral iron in treatment of postpartum iron deficiency anaemia.

Objectives

Primary : To compare the effectiveness of ferric carboxymaltose injection with oral iron by noting haemoglobin rise.

Secondary : To assess side effects in females receiving Ferric Carboxymaltose injection and those receiving oral iron.

METHODOLOGY

Venue of Study: Postnatal Ward of Department of Obstetrics and Gynaecology and Obstetrics and Gynaecology OPD of ESI-PGIMSR Basaidarapur, New Delhi.

Study Type: Prospective Comparative Study.

Study Duration: 18 months

Study Population: Postnatal women meeting the inclusion criteria will be included in the study after written informed consent in a language understood by the patient.

Sample Size:

Sample size of 100 per group is calculated to achieve 85% power to detect a difference of 20% [90% (parenteral group) versus 70% (oral group)] according to two-sided z test and pooled variance. The level of significance is 5%. After adding 15% lost to follow up, 100 per group is adequate sample size (total 200)

Sample size was calculated with the formula:-

$$n = \frac{(Z_{\alpha/2}+Z_{\beta})^2 \cdot (p_1(1-p_1)+p_2(1-p_2))}{(p_1-p_2)^2}$$

(Z_{\alpha/2}) is the Z-score for the chosen level of significance (a / 2) , which is 1.96 for a 5% significance level.

(Z_{\beta}) is the Z-score for the desired power (1 - beta) which is approximately 1.44 for desired power of 85% power.

(p_1) and (p - 2) are the proportions of success in each group (the probabilities of success for injectable and oral groups, respectively).

Therefore, the total sample size, considering the desired power, significance level is 86.7 and on adding 15% potential loss to follow up total sample size is approximately 99.705 per group. Hence we have taken 100 per group.

Inclusion criteria:

1. Postnatal women within 10 days of delivery.

2. Hb should be >7 gm% and ≤10 gm%.

3. Peripheral smear showing microcytic hypochromic anaemia or red cell indices suggestive of iron deficiency anaemia or Mentzer index >13.

Exclusion Criteria:

1. Puerperal pyrexia.

2. Known drug allergy or intolerance to iron therapy.

3. History of chronic medical illness.

4. Known cases of Thalassemia

5. Received other intervention for management of anaemia such as blood transfusion in last three months.

Withdrawal Criteria

If subject requires an intervention for management of anaemia such as blood transfusion, intravenous or oral iron outside the study protocol.

Methodology

All patients will undergo detailed history, general physical and systemic examination as per case record form (Annexure-II). Blood sampling will be done for red cell indices and liver function test. Patients will receive either intravenous ferric carboxymaltose or oral ferrous sulphate (hospital supply). Total dose of IV FCM will be calculated by Ganzoni formula[2].

Total dose of iron = body weight (in kg) x (14-baseline Hb) x 2.4 + 500

where, 14 target Hb (g/dl)

2.4 unitless conversion constant

500 target iron store in mg

Ferric carboxymaltose will be given as slow IV infusion, maximum single dose will not exceed 15 mg/kg or 1000 mg/dose in 200 ml of 0.9% normal saline over 15 minutes. During infusion, patient will be kept under strict observation with resuscitation measures available in ward. Patients will be observed for adverse effects during and 2 hours post transfusion. FCM will be repeated weekly up to calculated dose or maximum of 2500 mg

Second group of patients will be instructed to take ferrous sulphate tablet 200 mg (containing 60 mg elemental iron) twice times daily 1 hour before meal for 6 weeks. Patients will be observed for adherence to medication

Follow up

All patients will be followed at 4 and 6 weeks. Repeat Hb estimation will be done at 4 and 6 weeks while RBC indices and peripheral smear will be repeated at 6 weeks.

Methodology : Flow Chart

Post partum women screened for IDA (Hb, P/S, RBC indices)

(n=200)

(n=100) Injection Ferric carboxymaltose (as per calculated dose) using Ganzoni's formula

Total dose of iron- body weight(in kg) x (14-baseline Hb)x 2.4 + 500

Where , 14- target Hb 500- target iron store in mg

2.4- unitless conversion constant

Ferric carboxymaltose will be given as slow IV infusion, with maximum single dose will not exceed 1gram/dose in 200ml of 0.9% Normal Saline over 15 minutes. During infusion patients will be kept under strict observation for adverse effects and for next 2 hours post infusion.

(n=100) Oral ferrous sulphate (200 mg BD)

As per Systematic Randomization method patients will be randomized in 1:1 ratio with the help of centralized computer randomization to receive either Intravenous Ferric carboxymaltose or oral iron sulphate

At 4 week repeat Hb estimation

At 6 week repeat all investigations (Hb, RBC indices, peripheral smear)

Adverse effects will be recorded. Patients with adverse effects will be given alternative options of treatment but will excluded from the study thereafter. Changing of patients from one to other group will not be done.

Outcome measures:

Primary:

Rise in Hb from baseline to 4 and 6 weeks

Secondary:

Percentage of patients achieving Hb >11 g/dl at 4 and 6 weeks.

Percentage of patients achieving Hb rise >3 g/dl from baseline at 4 and 6 weeks

Change in red cell indices and peripheral smear from baseline to 6 weeks.

Side effects profile of injectable Ferric carboxymaltose injection and oral iron

Side effects in both the groups

Recording the side effects in both the groups such as dysgeusia, nausea, abdominal pain, urticaria, muscle cramps, headache, nasopharyngitis, fever, infusion site burning pain, serum transaminase elevation, etc will be done.

Statistical Methods and Data Management

Data will be analysed as per protocol and with intention to treat.

Baseline characteristics and treatment differences for means will be assessed with the Student t-test for independent groups, assuming equal variances. For the primary endpoint and other proportions, Fisher's exact test will be used. Logistic regression will be used to assess the effect of baseline characteristics on the primary endpoint. IBM SPSS version 24 software will be used for data analysis.

For all statistical comparison, a value of $p<0.05$ will be considered significant.

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ANNEXURE-I

PATIENT INFORMATION SHEET

You are being invited to participate in a research study. Before you take part in this research study, the study must be explained to you and you must be given the chance to ask questions. Please read carefully the information provided here. If you agree to participate, please sign the informed consent form. You will be given a copy of this document to take home with you.

STUDY INFORMATION:

TITLE: COMPARATIVE ANALYSIS OF ORAL IRON WITH INJECTABLE FERRIC CARBOXYMALTOSE FOR TREATMENT OF POST PARTUM IRON DEFICIENCY ANAEMIA

Investigator:-Dr Shreya Mahajan Contact No.- 8851826881

Supervisor: Dr Disha Andhiwal Rajput Contact No.- 9819720141

PURPOSE OF THE STUDY:

You are being invited to participate in a research study of postpartum iron deficiency anaemia We hope to learn efficacy of injectable ferric carboxymaltose over oral iron with for treatment of post partum iron deficiency anaemia

You were selected as a possible subject in this study because your investigations are showing you as iron deficient mild/moderate anaemic mother.

This study will recruit 200 subjects from ESI PGISMR, Basaidarapur, Delhi over a period of 18 months. About 200 subjects will be involved in this study.

STUDY PROCEDURE

- If you agree to take part in the study you will be included in the study.
- You will undergo history, general physical and systemic examination. You will be allocated either oral iron tablet or intravenous iron and 5ml your blood sample will be drawn for Complete Blood Count(CBC) with Peripheral Smear(2ml) and Liver Function Test(LFT) (3ml) will be taken at beginning, 2ml of blood for CBC at 4 weeks and 5ml of blood sample again for CBC and LFT at 6 weeks to assess improvement
- If you are discharges and are detected to have Iron deficiency anaemia within 10 days of delivery, you will have to get admitted for 1 -2 days if you are chosen to get ferric carboxymaltose injection for infusion and observation for adverse effects after which you will be discharged and followed up.

YOUR RESPONSIBILITIES IN THE STUDY

- Keep your study appointments. If it is necessary to miss an appointment, please contact the study staff to reschedule as soon as you know you will miss the appointment.
- Be prepared to visit the hospital as and when required.

WITHDRAWAL FROM THE STUDY

- You are free to withdraw your consent and discontinue your participation at any time without prejudice to you or effect on your medical care.
- If you decide to stop taking part in this study, you should tell the Principal Investigator.

<u>If you withdraw from the study,</u>

-Your name will be removed from the clinical proforma database.

Your doctor, the Principal Investigator and/or the supervisor of this study may stop your participation in the study at any time for one or more of the following reasons:

- Failure to follow the instructions of the Principal Investigator and/or study staff
- The Principal Investigator decides that continuing your participation could be harmful.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.
- Pregnancy

POSSIBLE DISCOMFORTS AND INCONVENIENCES

- There are risks, discomforts and inconveniences associated with any research study.
- Intravenous iron infusion will not cause much pain or discomfort. You will be observed during infusion.
- Oral iron has side effects like nausea, vomiting, constipation, abdominal pain etc. Intravenous iron has side effects like fever, diarrhoea, rashes, injection site problem, headache, muscle cramp, urticaria.

POTENTIAL BENEFITS OF THE STUDY

If you participate in this trial you may reasonably expect to benefit from the trial of injectable FCM or oral iron in the following way: as it will gradually correct your iron deficiency anaemia and increase iron levels supporting overall health.

ALTERNATIVES

You are free not to participate in the study or to withdraw from the study at any time. If you choose not to participate or withdraw from the study, you will receive the usual standard care.

SUBJECT'S RIGHTS

Your participation in this study is entirely voluntary. Your questions will be answered clearly and to your satisfaction.

In the event of any new information becoming available that may be relevant to your willingness to continue in this study, you will be informed in a timely manner by the Principal Investigator.

By signing and participating in the trial, you do not waive any of your legal rights to revoke your consent and withdraw from the trial at any time.

CONFIDENTIALITY OF STUDY AND MEDICAL RECORDS

Information collected for this study will be kept confidential. Your records, to the extent of the applicable laws and regulations, will not be made publicly available. Only your Investigator will have access to the confidential information being collected.

However, Regulatory Agencies, Institution Review Board and Ministry of Health will be granted direct access to your original medical records to check study procedures and data, without making any of your information public. By signing the Informed Consent Form attached, you are authorizing such access to your study and medical records.

Data collected are the property of the institution. In any publication regarding this study, your identity will remain confidential.

COSTS OF THE PARTICIPATION

If you take part in this study, the procedures and investigations that you will be asked to undergo during the study will be provided free of cost to you. You will not receive any compensation for participating in this study.

RESEARCH RELATED INJURY AND COMPENSATION

The Hospital does not make any provisions to financially compensate trial subjects for research-related injury. However, you would be treated for the same at no additional costs at this hospital.

WHO TO CONTACT IF YOU HAVE QUESTIONS OR FEEL UNDER PRESSURE TO CONTINUE AGAINST YOUR WISHES

If you have questions about this research study and your rights or in the case of any injuries during the course of this study or In the event that at any time during the course of the study you feel that you have not been adequately informed about the risks, benefits, alternate procedures or rights as a study subject or feel under pressure to continue against your wishes, you can contact the Principal Investigator OR the supervisor:

Investigator:- Dr Shreya Mahajan Contact no.- 8851826881

Signature of the investigator……..

Supervisor:- Dr Disha Andhiwal Rajput Contact no. 9819720141

Signature of the supervisor…….

ANNEXURE-II

CASE RECORD FORM

Name: Age:

Address:

Husband's Name: Religion:

Date: Tel No.:

Hospital Reg. No.

Education status:

Occupation:

Socioeconomic status:

Menstrual history:

Obstetric history:

Medical history:

Personal history:

Dietary history:

Vegetarian / non-vegetarian

Known drug allergy or intolerance:

Examination

A. General physical examination

1. General condition

2. Height

3. Weight

4. BMI

5. Pulse

6. BP

7. Pallor

8. Icterus

9. Lymphadenopathy

10. Signs of iron/vitamin deficiency

11. Thyroid

12. Breast

B. Systemic examination

1. Respiratory system

2. Cardiovascular system

3. Abdominal examination

4. Per vaginal

Investigations

BG

	At presentation	At 4 weeks	At 6 weeks
Hb			
PCV			
RBC count			
MCV			
MCH			
MCHC			
Platelet count			
TLC			
Retic count			
Peripheral smears			
LFT			
Serum Bilirubin			

SGOT

SGPT

Side effects

• Nausea

Vomiting

Fever

Abdominal pain

Diarrhea

Constipation

Injection site problem

Rashes

Headache

Dysguesia

Urticaria

Muscle cramps

Headache

Nasopharyngitis

Any other

ANNEXURE - III

CONSENT FORM

I _____ age _____ resident of _____, give my free and voluntary consent to be included in the clinical study labelled "Comparative analysis of oral iron with injectable ferric carboxymaltose for treatment of postpartum iron deficiency anaemia". I have been explained in the language I understand to my full satisfaction about the nature and purpose of investigations by the Doctor Shreya Mahajan. I have been explained that a set of questions will be asked regarding my disease and examination will be done and my confidentiality will be maintained in the study. Blood samples will be taken during the study. During the course of the study, I will give my cooperation to the concerned doctor and the hospital staff. I give my consent for the publication of the results of the study.

I give full consent for being enrolled in the above study and I reserve my rights to withdraw from the study whenever I wish without prejudice of my right to undergo further treatment at ESI Hospital, Basaidarapur, New Delhi.

Date and time: ……

Patient's details:

Name……

Address……

Contact No……..

Signature/Thumb impression……..

Witness's details:

Name……..

Address……..

Contact No……..

Signature/Thumb impression……..

Name of Doctor:- Dr Shreya Mahajan Contact no:- 8851826881

Supervisor:- Dr Disha Andhiwal Rajput Contact no. 9819720141

University School of Medicine and Paramedical Health Sciences
Guru Gobind Singh Indraprastha University, New Delhi
Candidate's Checklist
{to be filled and attached as a part of the thesis protocol }

Name: Dr. SHREYA MAHAJAN **Course:** MD/MS OBGYN **Institution:** LESIL - PGIMSR BASAIDARAPUR.
Title of the Thesis Protocol: COMPARATIVE ANALYSIS OF ORAL IRON WITH INJECTABLE FERRIC CARBOXYMALTOSE FOR TREATMENT OF POST PARTUM IRON DEFICIENCY ANAEMIA.

S. No.	Checklist for Thesis Protocol	Place (√) or (×)
	Title Page of the Protocol	
1.	Does the title reflect the aims and objective(s) of the proposal?	✓
2.	Does the title page include your name, course, batch year, college, university?	✓
	First Preliminary Page of the Protocol	
3.	Does the page carry your name and signature?	✓
4.	Does the page carry the name, university designation and signature of your thesis supervisor?	✓
5.	Does the page carry the name, university designation and signature of the co-supervisor/s?	
6.	Does the page carry the name and signature of your Head of Department?	✓
7.	Does the page carry the name and signature of your Head of Institution?	
	Undertaking and Certificates	
8.	Have you attached the declaration (5.5.1) that the thesis protocol does not violate the copyright act in any way, is free of plagiarism, and you've not reproduced any "questionnaires", "scores", diagrams, figures, tables, flowcharts which may infringe the copyright act?	✓
9.	Have you attached your supervisor's and co-supervisors certificate (5.5.2) that they would supervise and guide your work?	✓
10.	Have you attached certificate (5.5.3) bearing your own, your supervisor's, your co-supervisors' and Head of Department's signatures asserting the feasibility of the study; the study sample size having been calculated on the basis of relatable statistical formula and satisfying the requirements of study design and the proposed statistical analysis; the thesis plan not being a repetition of a similar work undertaken in the previous 5 years; the plan not entailing a retrospective collection or analyses of data from old patient case records; not employing any "off-label drug trial"; assertion that participants would not bear any financial burden on account of the investigations, devices, implants or drugs employed; and that the study would not require you to take any obligation from a pharmaceutical company, device manufacturer or medical supplier?	✓
11.	Have you attached the certificates of your Institutional Review Board (IRB)/Thesis Protocol Review Board (5.5.4) and Institutional Ethics Committee (IEC) (5.5.5) conveying their formal approval of the project in the study protocol?	✓
	Table of Content	
12.	Have you drawn a table of contents and numbered all pages of the protocol in the following sequence: ➡Introduction; ➡Review of Literature; ➡Lacunae in existing knowledge; ➡Research question and Hypothesis; ➡Aims and Objectives; ➡Material and Methods; ➡Statistical methods; ➡References; ➡Appendices?	✓
	Introduction	
13.	Have you provided a brief description of the existing knowledge on your research topic under "Introduction"?	✓
	Review of Literature (ROL)	
14.	Have you exhaustively reviewed the current literature on the research topic and presented a comprehensive summary of the current knowledge in a lucid manner under the Review of Literature?	✓
	Research Question and Hypothesis	
15.	Have you clearly stated the research question that you wish to resolve?	✓
16.	Does the hypothesis match the research question and is it based on a sound scientific presumption?	✓
	Aims and Objectives	
17.	Have you clearly stated the Aims and Objectives of the study?	✓
18.	Is the Aim in accordance with the research topic?	✓
19.	Are the Primary Objectives clearly stated?	✓
20.	Are the Secondary Objectives clearly stated?	✓
21.	Are the Objectives aligned with the research subject?	✓
22.	Are the Objectives achievable in a specified time frame?	✓
23.	Are the Objectives achievable within the existing resources?	✓
	Materials and Methods	
24.	Have you stated the place of study?	✓
25.	Have you stated the period of study?	✓
26.	Have you stated the type of study you're undertaking?	✓
27.	Does the stated study type match with the research design?	✓
28.	Is the study population defined?	✓
29.	Is the method of recruitment defined?	✓
30.	Are the inclusion criteria defined?	✓
31.	Are the exclusion criteria defined?	✓

32.	In studies where applicable, are the study groups defined?	✓
33.	Do you intend to employ a control group?	✓
34.	Is the control group suitably matched to the participants of the study?	✓
35.	Is the study sample size calculated on the basis of a sound relatable statistical formula?	✓
36.	Does the study sample size match the study design and statistical methods you propose to employ on the data?	✓
37.	Have you included a detailed study flow chart in the protocol?	✓
38.	Have you included the details of the proposed investigations and how they relate to your study?	✓
39.	Do you intend to carry out any interventions?	✓
40.	Have you included the details of the proposed interventions?	✓
41.	Do you have a gold standard to clinch the diagnosis?	✓
42.	How accurate is the gold standard?	
43.	Have you included the outcome measures?	
44.	Have you included any "clinical scores"?	✓
45.	If yes, are these "clinical scores" copyright free?	
46.	If copyrighted, have you taken steps to ensure you do not violate the copyright?	
	Statistical methods	
47.	Have you stated the statistical methods you would employ to gauze the obtained data?	✓
48.	Have you explained how the stated statistical methods would be employed to obtain results?	✓
	References	
49.	Have you numbered each reference beginning with page 1 of the introduction and till the end of the protocol in a continuous sequence in order of their appearance (as is prescribed in Vancouver style)?	✓
50.	Have you cited the references as they appear within the text in Arabic numerals in superscript?	✓
51.	Under the reference section, have you listed the details of each reference as is prescribed in Vancouver style?	✓
	Appendix	
52.	Does the protocol carry any questionnaire?	
53.	Is the questionnaire validated?	
54.	Is the questionnaire copyright free?	
55.	Have you included a detailed study pro forma to capture all significant elements of the study?	
	Patient Information sheet (PIS)	
56.	Have you included PIS in Hindi?	
57.	Have you included PIS in English?	✓
58.	Does the PIS state the purpose of the study?	✓
59.	Does it mention how it is going to benefit the participants?	✓
60.	Does it state the procedures and tests to be done?	✓
61.	Does it elaborate how the procedures and tests will be done?	✓
62.	Does it mention the potential side effects and/or risks?	✓
63.	Does it include your and your supervisor's name and contact number?	✓
64.	Have you clearly stated any know ethical issue(s)?	✓

	Patient Information sheet (PIS)	
56.	Have you included PIS in Hindi?	
57.	Have you included PIS in English?	✓
58.	Does the PIS state the purpose of the study?	✓
59.	Does it mention how it is going to benefit the participants?	✓
60.	Does it state the procedures and tests to be done?	✓
61.	Does it elaborate how the procedures and tests will be done?	✓
62.	Does it mention the potential side effects and/or risks?	✓
63.	Does it include your and your supervisor's name and contact number?	✓
64.	Have you clearly stated any know ethical issue(s)?	✓

	Informed Consent Form	
65.	Have you included an informed consent form in Hindi?	
66.	Have you included an informed consent form in English?	✓
67.	Does the informed consent form bear the name, address, contact number and signature of the participant?	✓
68.	Does the informed consent form bear the name, address, contact number and signature of a witness?	✓
	Binding	
69.	Is the thesis protocol firmly bound?	
	Candidate's Checklist	
70.	Have you submitted the filled up Candidate's Checklist in the bound thesis protocol?	✓

(DR SHREYA)
Signatures of the candidate with date

Signatures of the supervisor with date
24/2/24
Name of the supervisor
DR NISHA. ANUDHIKA RAJAK