HREC Assigned number: NHREC/01/01/2007
This approval will elapse on: 06/09/2023

PARTICIPANT INFORMATION SHEET

LAGOS UNIVERSITY TEACHING HOSPITAL

Ishaga Rd, Idi-Araba, Lagos.

Title of the research:
Intravenous ferric carboxymaltose versus oral ferrous sulphate for the treatment of postpartum anemia in Nigerian women (IVON-PP): an open labeled randomized controlled trial and implementation study.

Name(s) and affiliation(s) of researcher(s):
This study will be coordinated by Professor Bosede B. Afolabi, the Principal Investigator in the Dept. of Obstetrics and Gynaecology, College of Medicine of University of Lagos and Lagos University Teaching Hospital, Idi-Araba, Lagos.

Sponsor(s) of research:
College of medicine, University of Lagos.

Purpose(s) of research:
This study is to compare the effectiveness and benefits of using ferric carboxymaltose given in drip, with ferrous sulphate tablet in treating iron deficiency anaemia in women who delivered within the last 48 hours.

Procedure of the research, what shall be required of each participant and approximate total number of participants that would be involved in the research:
The research involves obtaining information from you directly by asking certain questions and using your answers to complete a form designed for this study. This initial assessment will take approximately 10 minutes of your time. We will also retrieve additional information from your case note where necessary. After this, blood samples will be drawn from your vein at specified times from the time you join the study until 6 months after delivery visit, to check your blood level, iron levels, and effects on your bones. We will update your records each time you come for your antenatal clinic. We will also follow up whenever you are on admission to monitor your progress and update your records. We will follow you up until 6 months after you have delivered.

A total of 1400 patients will be involved in this research. In total you will be required to make four (4) clinic visits after your first contact with the research team or we will make home visits, at your convenience. If for any reason you miss a visit that was agreed to be done at the clinic, we will try to reach you or a relative (whom you suggested at your first encounter) by calling you on the phone to find out why. If we are unable to get you on the phone, we will visit you at home to make enquiries regarding your missed visit and your wellbeing and collect the necessary information and blood specimens during the visit.

Please give a copy of the signed informed consent to the participant for keep.

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Expected duration of research and of participant(s)' involvement:
In total, we expect you to be involved in this research for 6 months. You should not spend more than 1 hour at each clinic or home visit.

Risk(s):
This study involves collecting your information in an electronic database designed for the study and collection of blood specimen from your veins using syringe and needle only. Therefore, the harm it poses to participants is minimal. The trial drugs too have been found to be safe for use after delivery and during breastfeeding and is currently being used in another research (IVON trial) in pregnant Nigerian women with no serious side effect documented so far. You are however free to call the investigators immediately (see contact details at the end of this pamphlet) if you notice any symptom, you are not sure of, or fear may be a side effect of medication.

Costs to the participants, if any, of joining the research:
Your participation in this research will not cost you anything as you will not be required to pay any fee for participating in the research, for investigations, or for drugs.

Benefit(s):
The blood test results, and study drugs will be given to you free at no cost while you are in the study. You will also get your folic acid and vitamin C free. You will have the opportunity of enjoying one-on-one contact with your health care providers as phone numbers will be exchanged. You will have the benefits of getting regular reminders of your appointments either via phone calls or text messages to minimize you missing clinic visits. Generally, you will enjoy a closer monitoring of your health while in the research. The result of this research might enable us to change our current methods for treatment of iron deficiency anaemia in women after delivery, improve the outcomes of anaemia treatment in mothers after delivery and lower the high maternal death rate in our environment. The findings will be presented at conferences to spread the findings to other health workers to improve scientific knowledge. The findings of this study will be published in reputable medical journals for wider dissemination of information.

Confidentiality:
All information obtained in this study will be kept strictly confidential by the principal investigator. Data will be stored in pass-worded electronic database. Your personal details will not be released in any publication or reports arising from this study.

Voluntariness:
Your participation in this research is entirely voluntary. You have a right to agree or decline to participate. Your refusal to participate will not in any way affected the quality of care you receive at the hospital.

Alternatives to participation:
We do not have any alternative to participating in the research. It is either you agree to participate, or you do not agree.

Due inducement(s):
You will not be paid any fees for participating in this research.

Consequences of participants' decision to withdraw from research and procedure for orderly termination of participation:
You may choose to withdraw from the research at any time. Please note that some of the information that has been obtained about you before you chose to withdraw will be used in reports and publications. However, the researchers promise to make good effort to comply with your wishes as much as is practicable. You only need to notify the research team at your hospital of your decision to withdraw if need be. It is however highly recommended you complete the research unless you have a strong to do otherwise.

Modality of providing treatments and action(s) to be taken in case of injury or adverse event(s):
If you suffer any injury as a result of your participation in this research, for instance a severe side effect confirmed to be due to the study drug, you will be treated at the hospital where you were enrolled for the study or referred to another hospital involved in the research if necessary, and the researchers will bear the cost of such treatment.

What happens to research participants and communities when the research is over:
The researcher will inform you of the outcome of the research. Important findings from the research may be used in building up health talks for pregnant women receiving antenatal care at various health facilities in Nigeria.

Statement about sharing of benefits among researchers and whether this includes or exclude research participants:
There is no benefit either in cash or kind to be shared among the researchers or among the patients as a motivating factor or inducement to partake in this research. The researchers also hereby declare that they are not deriving any benefit from the drug manufacturers for the use of specific drugs in the conduct of this research.

Any apparent or potential conflict of interest:
The researchers have no competing interest in conducting this research.

Central storage and future use of blood samples and study information
A small portion of the blood samples collected from you will be stored for a long time at the College of Medicine, University of Lagos Biospecimen Repository for current and future research that might include genetic research in which case your individual genetic results or incidental findings will not be shared with you. These tests will be research-related, and the

findings may need additional research before their clinical significance is understood, and appropriate actions are determined.

Data from the blood analysis from archived samples will be stored without identifiers and may be shared with secondary researchers within or outside the study sites.

Study data & document retention
A copy of the signed original informed consent documents for each participant, REDCap data and original copies of other study documentation (e.g., drug inventory forms, participant clinic records, laboratory reports, etc.) will be retained by the Principal Investigator for a minimum of 10 years.

For further enquiry, please contact:

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