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Assessing the effect of different doses of iron supplementation in pregnant women

Submission date
01/03/2017

Recruitment status
No longer recruiting

Registration date
13/03/2017

Overall study status
Completed

Last Edited
08/04/2020

Condition category
Haematological Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Anaemia is a condition in which there are not enough red blood cells or not enough of the component of blood that binds to oxygen (haemoglobin). Haemoglobin is made from iron and so a deficiency in iron can lead to a type of anaemia called iron-deficiency anaemia. Iron-deficiency anaemia during pregnancy is a common condition, particularly in developing countries where people often do not get adequate iron from their diets. Iron supplements are usually used to treat this condition, however they can have unpleasant side-effects such as nausea and constipation and so many women are reluctant to take them. To prevent the development of iron-deficiency anaemia during pregnancy, the World Health Organisation (WHO) recommends that pregnant women in developing countries should receive 60mg of iron every day from when they are 18 weeks pregannt. The aim of this study is to compare the effectiveness of once weekly supplementation of oral iron therapy against the current practice of daily supplementation in order to prevent iron-deficiency anaemia during pregnancy.

Who can participate?
Women who are 18 weeks pregnant who are not anaemic.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group are asked to take one iron tablet every day until they have their baby. Those in the second group take three iron tablets once each week until they have their baby. At the start of the study when women are 18 weeks pregnant and again when women are 37 weeks pregnant, women in both groups have blood samples taken to measure their iron levels. In addition, their baby's weight when born is also recorded.

What are the possible benefits and risks of participating?
There are no direct benefits to participants however taking part in this study will help increase knowledge about how best to give iron supplements to prevent iron-deficiency anaemia in pregnancy. There is a small risk that some participants may experience discomfort or bruising from blood tests.

Where is the study run from?
1. Obafemi Awolowo University Teaching Hospitals Complex (Nigeria)
2. Ladoke Akintola University of Technology Teaching Hospital (Nigeria)

When is the study starting and how long is it expected to run for?
May 2015 to May 2017

Who is funding the study?
Obafemi Awolowo University Teaching Hospitals Complex (Nigeria)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ERC/2015/09/05

Study information

Scientific Title
Serum ferritin level in non-anaemic pregnant women on daily versus weekly iron supplement: A randomized control trial

Study objectives

Weekly supplementation of 195mg of elemental iron is as effective as daily supplementation with 65mg elemental iron in maintaining normal serum ferritin level in pregnancy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Obafemi Awolowo University Teaching Hospital Ethics and Research Committee, 22/09/2015, ref: IRB/IEC/0004553

Study design
Single-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Iron deficiency anaemia in pregnancy

Interventions
Participants are randomised to one of two groups by allocating odd and even numbers to the participants at their antenatal booking clinic. Participantss with even number will be drafted to the daily group while those with even numbers will be allocated to the weekly group.

Arm 1 (daily group): Participants will receive one tablet of ferrous sulphate (Fesulf by Therapeutic pharmaceuticals, Lagos) 200mg BP equivalent to 65mg elemental iron once daily from 20 weeks of gestation until delivery.

Arm 2 (weekly group): Participants will receive three tablets of ferrous sulphate (Fesulf 200mg BP by Therapeutic pharmaceuticals, Lagos) at once on a particular day of the week from 18 weeks until delivery.

Blood samples for heamoglobin concentration and serum ferritin will be drawn from all participants in both arms at baseline (20 weeks gestation), and 37 weeks gestation.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Ferrous sulphate

Primary outcome measure
1. Serum ferritin level is measured using a fasting 5mls blood sample collected in a plain universal using Accu-Bind ELISA Microwells Ferritin Test System at baseline (20 weeks gestation), and 37 weeks gestation
2. Heamoglobin concentration will be measured using a capillary tube blood sample drawn at baseline (20 weeks gestation), and 37 weeks gestation

Secondary outcome measures
Baby's birthweight is measured using Seca 354 electronic baby weighing (Seca Cirencester UK) scale after delivery.

Overall study start date
22/05/2015

Completion date
22/05/2017

Eligibility

Key inclusion criteria
1. Pregnant women at an estimated gestation age of 18 weeks
2. Not anaemic
3. Haemoglobin genotype of AA or AS
4. Provision of informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
250 women

Total final enrolment
250

Key exclusion criteria
1. Exceeded the 20th week of pregnancy
2. Haemoglobin genotype SS or SC
3. Anaemic pregnant women with haemoglobin less than 100g/L
4. Those who are not willing to participate in the study

Date of first enrolment
30/09/2015

Date of final enrolment
30/01/2017

Locations

Countries of recruitment
Nigeria

Study participating centre
Obafemi Awolowo University Teaching Hospitals Complex
Ile-Ife
Nigeria
220005

Study participating centre
Ladoke Akintola University of Technology Teaching Hospital
Osogbo
Nigeria
360104

Sponsor information

Organisation
Obafemi Awolowo University Teaching Hospitals Complex

Sponsor details
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Sponsor type

Hospital/treatment centre

ROR
https://ror.org/05bkbs460

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Obafemi Awolowo University Teaching Hospital

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
01/01/2019

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results	results presented at RCOG World Congress	01/06/2019	08/04/2020	No	No