

# Treatment of iron deficiency anaemia in pregnancy study

<b>Submission date</b> 20/02/2019	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 25/06/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 12/09/2023	<b>Condition category</b> Haematological Disorders	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Over a third of pregnant women are anaemic by their third trimester of pregnancy. The most common cause is iron deficiency (low iron in the blood). The main reason is rising iron requirements throughout pregnancy. Anaemia can make pregnant women feel tired and unwell. There is some evidence that anaemia may also increase the risk of babies being born prematurely and/or underweight. The evidence shows that anaemia could also be a risk factor for stillbirth and neonatal death. It can also be a real problem around the time of delivery if a mother bleeds when she is already anaemic. This increases the chance of her anaemia carrying on after pregnancy leading to more risk of infections and problems with breast feeding. Also, in more severe cases there will be more need for a blood transfusion.

Although we know how to treat this type of anaemia we don't know how effective the treatment is, or how severe the side effects are for pregnant women. In fact, we know that many pregnant women are troubled by these side effects and thus don't take the iron in the recommended way. This study aims to better understand anaemia and how to use oral iron therapy for iron deficiency anaemia in pregnant women. This includes recording the effect of treatment on anaemia symptoms, side effects, and the level of success of iron therapy using several blood tests.

### Who can participate?

Anaemic pregnant women and those anaemic up to 6 weeks postpartum are invited to participate in this study and treated using an iron treatment schedule as described in national guidelines.

### What does the study involve?

Blood samples for routine care and research will be taken at each clinic visit and tested to better understand iron metabolism and to better predict the response to oral iron therapy during pregnancy. Women will be asked to complete three short questionnaires at each visit and complete a symptoms diary for 2-4 weeks whilst taking iron tablets.

### What are the possible benefits and risks of participating?

There is no risk to women and their fetus in taking part in this study as we are following routine

standard care and treatment of anaemia. There may be some inconvenience in completing the study diary and questionnaires. Some women might suffer side effects from the iron tablets, but they will be closely monitored by the research doctor who will give further advice on what to do.

Where is the study run from?

This study is run from the Royal Wolverhampton NHS Trust .

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

June 2018 to March 2020

Who is funding the study?

Rotha Abraham Trust

Who is the main contact?

Mr David Churchill

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Prof Simon Stanworth

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## Contact information

### Type(s)

Scientific

### Contact name

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## **Additional identifiers**

### **EudraCT/CTIS number**

Nil known

### **IRAS number**

### **ClinicalTrials.gov number**

NCT03725150

### **Secondary identifying numbers**

2018OBS100

## **Study information**

### **Scientific Title**

Iron deficiency anaemia in pregnancy: an observational study of tolerability, compliance with oral iron therapy and effects on haematological/biochemical markers

### **Acronym**

TIAP

### **Study objectives**

To better define the natural history and understand how to use oral iron therapy for iron deficiency anaemia in pregnant women. Specifically, the study will document the impact of treatment on symptomatology, the induction of side effects, and the utility of several haematological indices; haemoglobin, ferritin, transferrin saturation, reticulocyte haemoglobin concentration, alongside changes in new markers of iron homeostasis (hepcidin), which may better predict the success of treatment with iron.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 23/04/2018, the West Midlands - Black Country Research Ethics Committee (West Midlands - Black Country Research Ethics Committee, The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS; 0207 1048106, 0207 104 8102; nrescommittee.westmidlands-blackcountry@nhs.net), ref: 18/WM/0090.

### **Study design**

Prospective cohort study.

**Primary study design**

Observational

**Secondary study design**

Cohort study

**Study setting(s)**

Hospital

**Study type(s)**

Other

**Participant information sheet**

See study outputs table

**Health condition(s) or problem(s) studied**

Iron deficiency anaemia in pregnancy

**Interventions**

This study is an observational study of practice.

Anaemic pregnant women will be invited to participate in a study aiming to assess response and tolerability to current doses and schedules for oral iron, as recommended in national (BSH) guidelines. At follow-up clinic visits a full blood count will be performed as per standard care. The following assessment/tests will also be performed as part of this study:

1. Blood samples will be taken for subsequent detailed analysis of pathways of iron metabolism.
2. Participants will be asked to complete Quality of Life questionnaires (The World Health Organisation- Five Well-Being Index (WHO-5), and the Well-being in Pregnancy (WiP) questionnaire.)
3. An additional Questionnaire to investigate the barriers and enablers to taking oral iron therapy
4. Participants will be asked to complete a tolerability and symptom diary

Pregnancy and fetal outcome data will also be collected 8 weeks after birth. These data are collected routinely for this group of women.

**Intervention Type**

Drug

**Pharmaceutical study type(s)**

Not Applicable

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Ferrous sulphate

**Primary outcome measure**

The proportion of pregnant women who meet the criteria for a clinical response, defined as an increase in haemoglobin concentration of 10g/l measured using serum haemoglobin concentration at baseline and 2-4 weeks after the onset of iron therapy.

### **Secondary outcome measures**

1. The change in frequency and severity of symptoms associated with anaemia in pregnancy measured using The 'Anaemia in Pregnancy Assessment Questionnaire' at baseline and any subsequent visit/s (depending on how many visits required but a minimum of one visit measurement is required at 2-4 weeks after the onset of iron therapy).
2. The frequency and severity of side effects induced by iron therapy to treat anaemia measured using tolerability and symptom diary at baseline and any subsequent visit/s (depending on how many visits required but a minimum of one visit measurement is required at 2-4 weeks after the onset of iron therapy).
3. A measurement of compliance with currently recommended oral iron regimens prescribed in pregnancy measured using tolerability and symptom diary and the need for dose adjustments in line with BSCH guidelines at baseline and any subsequent visit/s (depending on how many visits required but a minimum of one visit measurement is required at 2-4 weeks after the onset of iron therapy)
4. To document the longitudinal changes in haemoglobin, red cell indices, iron, transferrin, ferritin, CRP, during a treatment course of oral iron measured using serum haemoglobin, red cell indices, iron, transferrin, ferritin, CRP concentration at baseline and any subsequent visit/s (depending on how many visits required but a minimum of one visit measurement is required at 2-4 weeks after the onset of iron therapy).
5. To investigate the changes in research biomarker serum hepcidin, and whether it can predict the response to oral iron measured by serum hepcidin at baseline and any subsequent visit/s (depending on how many visits required but a minimum of one visit measurement is required at 2-4 weeks after the onset of iron therapy).

### **Overall study start date**

01/12/2017

### **Completion date**

01/03/2020

## **Eligibility**

### **Key inclusion criteria**

1. Pregnant women (any stage during pregnancy up to 36 weeks) and women in the puerperium (within 6 weeks post-delivery)
2. Anaemia as defined by WHO criteria and described in British Society Haematology (BSH)/ British Committee for standards in Haematology (BCSH) guidelines.
  - 2.1. First trimester < 110g/l
  - 2.2. Second and third trimester < 105g/l
  - 2.3. Puerperium < 100g/l
3. Age: 18-45 years

### **Participant type(s)**

Patient

### **Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

45 Years

**Sex**

Female

**Target number of participants**

120

**Total final enrolment**

111

**Key exclusion criteria**

1. Presenting at or after 36 weeks
2. Affected by a (major) haemoglobinopathy e.g. B thalassaemia major sickle cell disease
3. Overt clinical signs of sepsis
4. Allergies to iron
5. Hyperemesis Gravidarum / persistent vomiting
6. Inflammatory conditions such as Crohns, ulcerative colitis, Systemic lupus erythematosus, Rheumatoid arthritis.
7. Chronic renal failure

**Date of first enrolment**

01/06/2018

**Date of final enrolment**

01/12/2019

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Royal Wolverhampton Hospitals NHS Trust**

New Cross Hospital,  
Wolverhampton,  
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# Sponsor information

## Organisation

The Royal Wolverhampton NHS Trust,

## Sponsor details

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## Sponsor type

Hospital/treatment centre

## ROR

<https://ror.org/05pjd0m90>

# Funder(s)

## Funder type

Charity

## Funder Name

Rotha Abraham Trust

# Results and Publications

## Publication and dissemination plan

The main report of this trial and any associated papers will be submitted for publication in high impact peer review journals within a year of study completion. In addition, results will be presented at national and international meetings/conferences.

## Intention to publish date

31/10/2023

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Mr David Churchill (david.churchill1@nhs.net) once the study write up and publications have been completed. The data will become available in 2021 once all the analyses and publications have been completed. It will be available for individual patient systematic

reviews. Consent was not obtained from the participants who would need to be contacted by those wishing to utilise the data. These data are anonymised.

## IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	version V1.2	24/05/2018	25/06/2019	No	Yes
<a href="#">Protocol file</a>	version 1.2	04/05/2018	25/10/2022	No	No
<a href="#">HRA research summary</a>			28/06/2023	No	No