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Iron supplementation in iron deficiency

Submission date	Recruitment status	[ ] Prospectively registered
22/10/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
18/05/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
28/03/2018	Haematological Disorders	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Annabel Nickol

Contact details
Oxford Centre for Respiratory Medicine
Churchill Hospital
Old Road
Headington
Oxford
United Kingdom
OX3 7LJ

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Protocol version 3.0

Study information

Scientific Title

A single blind, randomised controlled study of iron supplementation in iron deficient, but otherwise healthy, patients on hypoxic pulmonary vascular responses

Study objectives
The purpose of this study is to test the hypothesis that patients with iron deficiency have extra large increases in pulmonary artery systolic pressure (PASP) when hypoxic, and that giving an iron infusion restores the normal response. We will therefore study patients with iron deficiency, but otherwise in good health, and iron-replete healthy volunteers. They will be randomised to receive an infusion of iron or a saline placebo, with PASP measured in acute hypoxia before, at intervals, and after the infusion. We will also see if other symptoms sometimes seen with iron deficiency (fatigue and restless legs), get better after the infusion.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Mid and South Buckinghamshire Research Ethics Committee, 31/10/2009, ref: 08/H0607/66

Study design
Single-blind randomised placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Interventions
1. Seeking consent, followed by a medical history and examination
2. Subjective symptom assessment
3. Blood test
4. Spirometry
5. Echocardiography
6. Acute hypoxic exposure with measurement of oxygen saturations, endtidal carbondioxide and breathing
7. Insertion of intravenous cannula
8. Infusion of saline (carried out if patient is randomised to the control limb)
9. Infusion of iron (carried out in all patients randomised to the test limb, and also at the end of

the study offered to those who had been randomised to the control limb, as a therapeutic intervention)
10. Actigraphy (wearing small movement sensors like wrist watches around the ankles during sleep). Carried out in the participant's own home.

Study drug: Iron Carboxymaltose, up to 1000mg, once only.

Intervention Type
Supplement

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Iron supplementation

Primary outcome measure
Acute hypoxic PASP post- compared to pre-iron infusion, measured at days 1, 2, 8 and 15.

Secondary outcome measures
Measured at weeks 1, 2, 4 and 8:
1. Time course of euoxic and hypoxic PASP post-iron infusion
2. Erythropoietin, and acute hypoxic cardiac output and ventilation post- compared to pre-iron infusion
3. Incidence of restless legs syndrome in iron deficient patients and iron replete healthy volunteers, and changes in symptoms and nocturnal leg movements following an iron infusion
4. Magnitude and time course of relief of fatigue post-iron infusion

Overall study start date
09/11/2009

Completion date
14/10/2013

Eligibility

Key inclusion criteria
1. Willing and able to give informed consent for participation in the study
2. Men and women aged 18 - 50 years and generally in good health
3. Detectable tricuspid regurgitation on echocardiography (enabling measurement of pulmonary arterial pressure)

For iron deficient patients:
4. Iron deficiency, defined as a ferritin less than 15 µg/L

For iron replete healthy volunteers:
5. Normal iron status (for example ferritin greater than 40 µg/L, iron 20 - 150 ng/ml, total iron binding capacity 250 - 450 ng/ml, and transferrin saturation 20 - 50%)

Participant type(s)

Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
48

Key exclusion criteria
1. Haemoglobin less than 7.0 g/dl
2. Haemoglobinopathy
3. Hypoxia at rest or on walking (saturation of oxygen in arterial blood [SaO2] less than 94%) or significant co-morbidity that may affect haematinics, pulmonary vascular or ventilatory responses, e.g. current infection, a chronic inflammatory condition, known cardio-valvular lesion or pulmonary hypertension, chronic airflow limitation
4. A cause for iron deficiency requiring urgent investigation, such as a bowel malignancy
5. Exposure to high altitude (greater than 2,500 m) within the previous six weeks, or air-travel greater than 4 hours within the previous week
6. Current or recent iron supplementation or blood transfusion within the previous 6 weeks
7. Pregnancy or breast feeding

Date of first enrolment
09/11/2009

Date of final enrolment
14/10/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Oxford Centre for Respiratory Medicine
Oxford
United Kingdom
OX3 7LJ

Sponsor information

Organisation
University of Oxford

Sponsor details
Clinical Trials and Research Governance
Manor House
John Radcliffe Hospital
Headington
Oxford
England
United Kingdom
OX3 9DZ

Sponsor type
University/education

Website
http://www.admin.ox.ac.uk/rso/contactus/ctrg.shtml

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Industry

Funder Name
Syner-Med (Pharmaceutical Products) Ltd (UK)

Funder Name
The John Fell OUP Research Fund (UK)

Funder Name
The Medical Research Fund (UK)

Results and Publications

Publication and dissemination plan

28/03/2018: Study not published due to 'a frustrating p=0.07, meaning results were not definitive, however it led on to further work with an amended protocol’

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration