

Iron supplementation in iron deficiency

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Single-blind randomised placebo-controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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

United Kingdom

England

Study participating centre

Oxford Centre for Respiratory Medicine

Oxford

United Kingdom

OX3 7LJ

Sponsor information

Organisation

University of Oxford

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration