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The effect of long-term iron treatment on plasma isoprostanes in anaemic women

Submission date 30/08/2006	**Recruitment status** Stopped	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 06/10/2006	**Overall study status** Stopped	
Last Edited 04/02/2011	**Condition category** Haematological Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
ISOPFe

Study objectives
Serum non-transferrin-bound iron (NTBI) and plasma isoprostanes will be significantly increased in samples collected immediately following 200 mg FeSO4 (65 mg iron) daily for 28 days, compared with before treatment, and compared with a control group who will not receive iron treatment.

Parametric tests (paired Student's t-test and one-way Analysis Of Variance [ANOVA]) will be used to determine the change in serum NTBI, plasma F2-isoprostanes and haemoglobin from visit one (baseline) to visit two within the treatment group, and the difference in the change in variables between the treatment group and control group, from visit one to visit two.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Kings College London Research Ethics Committee will be looking at protocol on the 30th September 2006.

Study design
Intervention study with only one subject group.

Primary study design
Interventional

Secondary study design
Single-centre

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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

Interventions
Subjects with iron deficiency anaemia will be recruited and will be randomly assigned to either a treatment (n = 15) or control group (n = 15). Subjects in the treatment group will receive 200 mg FeSO4 (65 mg iron) once daily for 28 days. Controls will NOT receive a placebo, but will be

instructed not to change their diet/lifestyle habits over a period of 28 days. In these subjects, plasma isoprostanes and serum NTBI will be measured at the start of the start of the study, and 28 days after their allocation to the control group.

All subjects will be asked to complete a seven day estimated diet diary, starting on the day after their allocation to either the treatment or control group, in order to examine the relationship between dietary antioxidant intakes and isoprostane levels in all subjects.

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome measure
Plasma isoprostane concentration after daily iron treatment for 28 days.

Secondary outcome measures
The secondary outcome is serum NTBI. In addition to measuring the primary outcome (plasma isoprostanes) before and once after once daily ferrous sulphate treatment for 28 days, we will also measure serum NTBI before and once after daily ferrous sulphate treatment for 28 days in all subjects.

Overall study start date
15/11/2006

Completion date
15/07/2007

Reason abandoned (if study stopped)
Lack of funding

Eligibility

Key inclusion criteria
1. Females aged 18 to 50 years
2. Iron deficiency anaemia, defined as haemoglobin less than 12 g/dl, and mean corpuscular volume (MCV) less than 90 fl and serum ferritin less than 20 ug/l

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
16

Key exclusion criteria
1. Suffer from serious chronic illness
2. Body mass index above 30
3. Smoker
4. Taking prescription drugs including contraceptive medicines
5. Regularly take medicines containing aspirin or ibuprofen
6. Pregnant or breastfeeding or are planning to become pregnant in the next two months
7. Moderately/severely elevated cholesterol (more than 6.0 mmol/l), as these factors affect either iron absorption or plasma isoprostane concentration

Date of first enrolment
15/11/2006

Date of final enrolment
15/07/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Nutrition and Dietetics
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Sponsor information

Organisation
Kings College London (UK)

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University/education

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ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
University/education

Funder Name
Existing funds: C Geissler, School of Biomedical and Health Sciences, Kings College London (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration