

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

<b>Submission date</b> 30/08/2006	<b>Recruitment status</b> Stopped	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 06/10/2006	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 04/02/2011	<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**  
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 FeSO<sub>4</sub> (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 F<sub>2</sub>-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 FeSO<sub>4</sub> (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 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**

London

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**Sponsor information****Organisation**

Kings College London (UK)

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**Sponsor type**  
University/education

**Website**  
<http://www.kcl.ac.uk>

**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