

Intravenous iron sucrose (+/- erythropoetin) versus oral iron for correction of post-operative anaemia in women with gynaecological malignancies

Submission date 30/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 30/09/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 13/03/2014	Condition category Haematological Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<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

Contact name

Dr Philip Barclay

Contact details

Anaesthesia Department
Liverpool Women's Hospital
Crown Street
Liverpool
United Kingdom
L8 7SS

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0128158020

Study information

Scientific Title

Study objectives

1. To see whether anaemia following major gynaecological cancer surgery can be treated more effectively using two injections of an intravenous iron preparation instead of a 6-week course of iron tablets
2. To see whether adding erythropoetin as well as intravenous iron is more effective than using intravenous iron alone

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Anaemia

Interventions

Randomised controlled trial:

1. Group O will receive a 6 week course of oral iron therapy
2. Group I will receive a 200 mg intravenous dose of iron sucrose
3. Group E will receive a 200 mg dose of iron sucrose followed by 200 IU/Kg epoetin alpha

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Iron sucrose (+/- erythropoetin), oral iron

Primary outcome measure

1. Change in haemoglobin levels from day 1 to day 21
2. Change in ferritin concentration
3. Change in transferritin
4. Quality of life scores
5. Post-operative blood transfusion
6. Length of stay

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/03/2005

Completion date

01/03/2007

Eligibility

Key inclusion criteria

45 patients in 3 groups.

1. Pre-operative inclusion criteria:
 - 1.1. All patients who are due to undergo major gynae-oncological surgery
 - 1.2. Aged greater than 18 years
2. Post-operative inclusion criteria:
 - 2.1. Iron deficiency type anaemia due to peri-operative blood loss
 - 2.2. Haemoglobin (Hb) less than 10 g/dl on day 1 following surgery

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

45

Key exclusion criteria

1. Pre-operative exclusion criteriaL
 - 1.1. Patients requiring peri-operative therapeutic anti-coagulant therapy
 - 1.2. Pre-operative anaemia
 - 1.3. Liver disease
 - 1.4. Chronic renal failure
 - 1.5. Uncontrolled hypertension
 - 1.6. Ischaemic heart disease requiring a transfusion threshold above 7 g/dl
 - 1.7. History of anaphylaxis to oral iron sulphate, iron sucrose or epoietin alpha
2. Post-operative exclusion criteria:
 - 2.1. Severe anaemia requiring transfusion of red cells: Day 1 [Hb] less than 7
 - 2.2. Massive blood transfusion associated with disseminated intravascular coagulation (DIC)
 - 2.3. Continuing requirement for blood product administration

Date of first enrolment

01/03/2005

Date of final enrolment

01/03/2007

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Anaesthesia Department

Liverpool

United Kingdom

L8 7SS

Sponsor information

Organisation

Department of Health

Sponsor details

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

+44 (0)20 7307 2622

dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type

Government

Funder Name

Liverpool Women's Hospital NHS Trust (UK)

Funder Name

NHS R&D Support Funding (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