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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	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 30/09/2005	**Overall study status** Completed	
Last Edited 13/03/2014	**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

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
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Sponsor information

Organisation
Department of Health

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Richmond House
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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