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Blood transfusion reduction with intravenous iron in gynaecological cancer patients receiving chemotherapy

Submission date 22/09/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 01/10/2009	**Overall study status** Completed	
Last Edited 12/09/2011	**Condition category** Cancer	

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
Blood transfusion reduction with intravenous iron in gynaecological cancer patients receiving chemotherapy: a randomised controlled trial

Study objectives
Chemotherapy-induced anaemia is common in gynaecological cancer patients. Blood transfusion is the main treatment for this, however it has some serious adverse events. Most of the patients who have had a blood transfusion for chemotherapy-induced anaemia continue to require transfusions in the consecutive cycles.

This randomised controlled trial is aimed at exploring whether intravenous iron could reduce the need for blood transfusions in anaemic gynaecological cancer patients receiving platinum-based chemotherapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Chulalongkorn University approved on the 28th August 2008 (ref: 237/51)

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Chemotherapy-induced anaemia

Interventions
Study group: Iron sucrose 200 mg intravenous drip over 30 minutes as a single dose
Control group: Ferrous sulphate 200 mg oral three times a day until the next cycle of chemotherapy

Patients will be contacted every week for monitoring of their complete blood count until the next cycle of chemotherapy (3 - 4 weeks depending on the chemotherapy regimen).

Intervention Type

Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Intravenous iron

Primary outcome measure
The incidence of blood transfusion at the consecutive cycle of chemotherapy between oral and intravenous iron, measured at the time of next cycle of chemotherapy (3 - 4 weeks depending on the chemotherapy regimen).

Secondary outcome measures
In both groups, assessed at the next cycle of chemotherapy (3 - 4 weeks depended on the chemotherapy regimen):
1. Haemoglobin and haematocrit increment
2. Number of blood transfusion units
3. Adverse events
4. Quality of life (QOL), also measured before treatment

Overall study start date
31/08/2008

Completion date
31/07/2009

Eligibility

Key inclusion criteria
1. Female participants aged 20 - 65 years
2. Normal liver function
3. Normal kidney function
4. No prior radiotherapy or having received radiotherapy
5. At least one remaining cycle of chemotherapy

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
44 patients

Key exclusion criteria

1. Iron hypersensitivity
2. Risk of iron overload such as chronic renal failure or thalassaemia major
3. Progressive disease
4. Bone marrow metastasis
5. Inability to monitor weekly complete blood counts

Date of first enrolment
31/08/2008

Date of final enrolment
31/07/2009

Locations

Countries of recruitment
Thailand

Study participating centre
1873 Rama IV, Patumwan
Bangkok
Thailand
10330

Sponsor information

Organisation
Chulalongkorn University (Thailand)

Sponsor details
Faculty of Medicine
Department of Obstetrics and Gynaecology
1873, Rama IV, Patumwan
Bangkok
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10330

Sponsor type
University/education

Website
http://chula.ac.th/chula/th/index_king60.html

ROR
https://ror.org/028wp3y58

Funder(s)

Funder type
University/education

Funder Name
Chulalongkorn University (Thailand) - Department of Obstetrics and Gynaecology, Faculty of Medicine

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