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

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

**Plain English summary of protocol**Not provided at time of registration

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Contact information

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**Type(s)**Scientific

#### Contact name

Dr Tarinee Manchana

#### Contact details

1873 Rama IV, Patumwan Bangkok Thailand 10330

## 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

#### 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 Thailand 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