

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

<b>Submission date</b> 22/09/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 01/10/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 12/09/2011	<b>Condition category</b> Cancer	<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

**Protocol serial number**  
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

### **Study type(s)**

Treatment

### **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(s)**

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).

### **Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

Female

**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)

**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**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**  
Not provided at time of registration