

# A phase II study of up-front red blood cell transfusion before chemotherapy followed by maintenance Erythropoetin-alpha subcutaneous support during chemotherapy of anaemic breast-, colorectal- and ovarian cancer patients

<b>Submission date</b> 27/02/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 27/02/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 20/08/2021	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

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

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

**Protocol serial number**

N/A

## **Study information**

**Scientific Title**

A phase II study of up-front red blood cell transfusion before chemotherapy followed by maintenance Erythropoetin-alpha subcutaneous support during chemotherapy of anaemic breast-, colorectal- and ovarian cancer patients

**Acronym**

pCATS

**Study objectives**

An upfront Red Blood Cell Transfusion (RBCT) aiming at low-normal Haemoglobin (Hb) levels will ameliorate anemia-caused tumour hypoxia-related resistance to chemotherapy before the start of chemotherapy and may decrease secondary anemia-induced endogenous release of cytokines like Vascular Endothelial Growth Factor (VEGF), osteopontin. The maintenance of optimal Hb levels at this lower-normal range during chemotherapy by weekly maintenance administration of Erythropoetin-alpha (Epo-alpha) subcutaneous (s.c.) at doses with proven safety and efficacy creates optimal conditions for tumour oxygenation, without the presumably high-Hb level associated adverse effects.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Ethics approval received from the local medical ethics committee

**Study design**

Phase II, non-randomised, non-controlled, multicentre clinical trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Breast cancer, colorectal cancer, ovarian cancer

**Interventions**

Anemia-treatment consisting of preventive RBCT before the start of chemotherapy followed by the maintenance administration of Epo-alpha s.c. during chemotherapy.

**Intervention Type**

Drug

**Phase**

Phase II

**Drug/device/biological/vaccine name(s)**

Erythropoetin-alpha

**Primary outcome(s)**

1. Hb levels before the start of and during chemotherapy
2. Safety of the pCATS anaemia treatment regimen

**Key secondary outcome(s)**

1. Global Quality of Life (QoL) determined by a measurement on a Linear visual Analog Scale Assessment (LASA)
2. Length of treatment duration and time to treatment failure

**Completion date**

01/09/2006

**Eligibility****Key inclusion criteria**

1. Histological or cytological documentation of breast- or colorectal- or ovarian cancer
2. Age greater than or equal to 18 years
3. Eastern Cooperative Oncology Group (ECOG) performance status of zero, one or two
4. Being scheduled to receive chemotherapy or having received already one cycle of chemotherapy and being scheduled to receive at least three cycles of chemotherapy prior to study entry
5. Life expectancy of at least six months
6. Signed written informed consent obtained prior to study entry
7. Anaemia: Hb less than 7.0 mmol/L tested within seven days before enrolment
8. Adequate bone marrow function as assessed within seven days before enrolment by:
  - a. absolute neutrophil count greater than or equal to  $1.5 \times 10^9/L$
  - b. platelets greater than or equal to  $100 \times 10^9/L$
9. Iron status measurements including levels of ferritin, transferrin, iron and iron saturation within seven days after enrolment
10. Patient is able to comply with scheduled follow up

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

Not Specified

### **Key exclusion criteria**

Excluded medical conditions:

1. Having more than one cycle of the current chemotherapy administered prior to inclusion
2. Having one cycle of chemotherapy administered before inclusion and scheduled to receive less than three additional cycles
3. Untreated folate or cobalamin deficiency
4. Untreated haemolytic anaemia defined by decreased serum haptoglobin levels
5. Anaemia due to hypoproliferative or maturation bone marrow disorders
6. Clinically evident untreated congestive heart failure
7. Serious, untreated cardiac arrhythmias
8. Symptoms of untreated coronary heart disease or ischaemia
9. Untreated hypertension
10. History of HIV infection

Excluded therapies, medications and conditions, previous and concomitant:

11. Androgen treatment within two months before enrolment
12. Anti-cancer chemotherapy or immunotherapy within four weeks of study entry
13. Darbepoetin or erythropoetin treatment within four weeks before enrolment
14. Bone marrow transplantation or stem cell transplantation within four months of study entry
15. Investigational drug therapy within four weeks of study entry or during this study
16. Pregnant or breast-feeding patients. Women of childbearing potential must have a negative pregnancy test performed within seven days of the start of treatment. Adequate birth control measures will be required during the course of the trial
17. Known or suspected allergy to Epo-alpha

### **Date of first enrolment**

15/09/2005

### **Date of final enrolment**

01/09/2006

## **Locations**

### **Countries of recruitment**

Netherlands

### **Study participating centre**

**t Lange Land Ziekenhuis**

Zoetermeer

Netherlands

2700 KJ

## **Sponsor information**

## Organisation

Leiden University Medical Centre (LUMC) (The Netherlands)

## ROR

<https://ror.org/027bh9e22>

## Funder(s)

### Funder type

Industry

### Funder Name

Comprehensive Cancer Centre (Integraal Kankercentrum) (The Netherlands)

### Funder Name

Janssen Cilag B.V. (The Netherlands)

### Funder Name

Ortho Biotech (USA)

## Results and Publications

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Abstract results</a>		20/05/2011	20/08/2021	No	No