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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
27/02/2007		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
27/02/2007	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
20/08/2021	Cancer			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

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 haptoglobulin 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?
Abstract results		20/05/2011	20/08/2021	No	No