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

Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Multi-centre

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
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

Overall study start date
15/09/2005

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 x 10^9/L
b. platelets greater than or equal to 100 x 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

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
23

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)

Sponsor details
Department of Clinical Oncology
P.O. Box 9600
Leiden
Netherlands
2300 RC

Sponsor type
Hospital/treatment centre

Website
http://www.lumc.nl/english/start_english.html

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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results		20/05/2011	20/08/2021	No	No