A phase II study of up-front red blood cell transfusion followed by maintenance Erythropoetin-alpha (Epo-alpha) s.c. support during chemotherapy of solid tumors.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26479

Source
NTR

Brief title
pCATS

Health condition

Solid tumors

Sponsors and support

Primary sponsor: Not applicable.
Source(s) of monetary or material Support: Ortho Biotech / Jansen-Cilag B.V., the Comprehensive Cancer Center West (Integraal Kankercentrum West)

Intervention

Outcome measures

Primary outcome

Hb levels before the start of and during chemotherapy; safety of the pCATS anemia treatment regimen.

Secondary outcome

Global QoL determined by a measurement on a linear visual analog scale assessment (LASA), length of treatment duration and time to treatment failure.

Study description

Background summary

Supportive care treatment of anemia with a blood transfusion before the start of standard chemotherapy, maintained with weekly erythropoetin-alpha subcutaneously injections during the duration of the chemotherapy

Study objective

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

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

1. Histological or cytological documentation of solid tumor (breast- or colorectal- or ovarian- or lung- or esophageal- or stomach- or bladder- or prostate- or germ cell- or cervical cancer or sarcoma)
2. Age >= 18 years;
3. ECOG performance status of 0, 1 or 2;
4. Being scheduled to receive chemotherapy or having received already 1 cycle of chemotherapy and being scheduled to receive at least 3 cycle of chemotherapy prior to study entry;
5. Life expectancy of at least 6 month;
6. Signed written informed consent obtained prior to study entry;
7. Anemia: Hb <7.0 mmol/L tested within 7 days before enrolment;
8. Adequate bone marrow function as assessed within 7 days before enrolment by:
a. Absolute neutrophil count >=1.5x10 9/L;
b. Platelets >= 100x10 9/L;
9. Iron status measurements including levels of ferritin, transferrin, iron and iron saturation within 7 days after enrolment;
10. Patient is able to comply with scheduled follow up.

Exclusion criteria

Excluded medical conditions:
1. Having more than 1 cycle of the current chemotherapy administered prior to inclusion;
2. Having 1 cycle of chemotherapy administered before inclusion and scheduled to receive less than 3 additional cycles;
3. Untreated folate or cobalamin deficiency;
4. Untreated haemolytic anemia defined by decreased serum haptoglobulin levels;
5. Anemia 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 ischemia;
9. Untreated hypertension;
10. History of HIV infection.

Excluded therapies, medications and conditions, previous and concomitant:
11. Androgen treatment within 2 month before enrolment;
12. Anti-cancer chemotherapy or immunotherapy within 4 weeks of study entry;
13. Darbepoetin or erythropoetin treatment within 4 weeks before enrolment;
14. Bone marrow transplantation or stem cell transplantation within 4 months of study entry;
15. Investigational drug therapy within 4 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 7 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.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-09-2005
Enrollment:	23
Type:	Actual

Ethics review

Positive opinion

Date:	19-09-2005
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL369
NTR-old	NTR409
Other	: N/A
ISRCTN	ISRCTN81146641

Study results

Summary results
N/A