Randomized study on hemoglobin response in iron-deficient anemic patients with solid maglignancies receiving epoetin alfa (rHuEPO) in combination with either oral or parental iron supplementation during treatment with non-platinum containing chemotherapy.

No registrations found.

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

Summary

ID

NL-OMON26767

Source
NTR

Brief title
N/A

Health condition

IJzerdeficiente anemische patiënten met solide tumoren

Sponsors and support

Primary sponsor: VU medisch centrum
Source(s) of monetary or material Support: VU medisch centrum

Intervention

Outcome measures

Primary outcome

Increase in Hb.

Secondary outcome

Number of required blood transfusions, total dose of administered rHuEPO.

Study description

Background summary

N/A

Study objective

To determine optimal route of iron supplementation during treatment with non-platinum containing chemotherapy for solid tumors.

Intervention

Epoetine alfa, iron (III)-hydroxyde-sucrose, ferrofumarate.

Contacts

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Eligibility criteria

Inclusion criteria

1. Confirmed diagnosis of a solid malignancy and planned to receive further non-platinum containing chemotherapy for at least 12 weeks;

2. Hb ¡Ü7.5 mmol/L at any time during chemotherapy;

3. TSAT <20% and/or serum ferritin < 100 ng/ml;

4. ECOG Performance Status of 0, 1 or 2;

5. Life expectancy at least 3 months;

6. Age between 18-75 years;

7. Sex: male or female. Female subjects must be either postmenopausal (for at least for 1 year), sterilised or, if of childbearing potential, be practising an acceptable method of birth control;

8. Subjects must have read and signed the informed consent form.

Exclusion criteria

1. MCV <80fL and MCHC <19.5 mmol/L;

2. MCV > 100fL;

3. Clinically significant chronic blood loss;

4. Clinically significant disease/dysfunction of the pulmonary, cardio-vascular, endocrine, neurological, gastrointestinal, or genitourinary systems not attributable to underlying malignancy or chemotherapy. This dysfunction is only an exclusion criteria if it causes an expected early withdrawal from the study;

5. Uncontrolled hypertension, defined as a diastolic blood pressure greater than 100 mmHg, despite antihypertensive medication;

6. History of seizures;

7. Known hypersensitivity to Epoetin alfa or one of its components;

8. Administration of intravenous iron preparations within 3 months before study entry;

9. Participation in any other clinical trial involving unlicensed medication or procedures;

10. Androgen therapy within two months of study entry.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2001
Enrollment:	34
Type:	Actual

Ethics review

Positive opinion

Date:	07-09-2005
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	NL214
NTR-old	NTR250
Other	: N/A
ISRCTN	ISRCTN61345286

Study results

Summary results
N/A