

Randomised study on haemoglobin response in iron-deficient anaemic patients with solid malignancies receiving epoetin alfa (rHuEPO) in combination with either oral or parental iron supplementation during treatment with non-platinum containing chemotherapy

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| Submission date 20/12/2005 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 20/12/2005 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 15/08/2008 | Condition category Haematological Disorders | <input type="checkbox"/> Statistical analysis plan |
| | | <input type="checkbox"/> Results |
| | | <input type="checkbox"/> Individual participant data |
| | | <input type="checkbox"/> Record updated in last year |

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number

NTR250

Study information

Scientific Title**Study objectives**

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

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Primary study design

Interventional

Study design

Multicentre, randomised, active controlled, parallel group trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Anaemia

Interventions

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

Intervention Type

Supplement

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Iron supplementation, Epoetine alfa, iron (III)-hydroxyde-sucrose, ferrofumarate

Primary outcome(s)

Increase in Hb

Key secondary outcome(s)

1. Number of required blood transfusions
2. Total dose of administered recombinant human erythropoietin alpha (rHuEPO)

Completion date

30/07/2003

Eligibility

Key inclusion criteria

1. Confirmed diagnosis of a solid malignancy and planned to receive further non-platinum containing chemotherapy for at least 12 weeks
2. Haemoglobin (Hb) less than or equal to 7.5 mmol/L at any time during chemotherapy
3. Transferrin saturation (TSAT) less than 20% and/or serum ferritin less than 100 ng/ml
4. Eastern Cooperative Oncology Group (ECOG) performance status of 0, 1 or 2
5. Life expectancy at least 3 months
6. Aged 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

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Mean corpuscular volume (MCV) less than 80 fL and mean corpuscular haemoglobin count (MCHC) less than 195 mmol/L
2. MCV greater than 100 fL
3. Clinically significant chronic blood loss
4. Clinically significant disease/dysfunction of the pulmonary, cardiovascular, 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

Date of first enrolment

01/02/2001

Date of final enrolment

30/07/2003

Locations

Countries of recruitment

Netherlands

Study participating centre**VU Medical Centre**

Amsterdam

Netherlands

1007 MB

Sponsor information

Organisation

Vrije University Medical Centre (VUMC) (The Netherlands)

ROR

<https://ror.org/00q6h8f30>

Funder(s)

Funder type

University/education

Funder Name

Vrije University Medical Centre (VUMC) (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration