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 nonplatinum containing chemotherapy

Submission date 20/12/2005	Recruitment status No longer recruiting	 Prospectively registered Protocol
Registration date 20/12/2005	Overall study status Completed	 Statistical analysis plan Results
Last Edited 15/08/2008	Condition category Haematological Disorders	 Individual participant data 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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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 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

Study design Multicentre, randomised, active controlled, parallel group trial

Primary study design Interventional

Secondary study design Randomised controlled trial

Study setting(s) Hospital

Study type(s) Treatment

Participant information sheet

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 measure Increase in Hb

Secondary outcome measures

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

Overall study start date

01/02/2001

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

Patient

Age group

Adult

Lower age limit 18 Years

Sex

Both

Target number of participants 34

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

1007 MB

Locations

Countries of recruitment Netherlands

Study participating centre VU Medical Centre Amsterdam Netherlands

Sponsor information

Organisation Vrije University Medical Centre (VUMC) (The Netherlands)

Sponsor details

Van der Boechorststraat 7 Amsterdam Netherlands 1081 BT

Sponsor type

University/education

Website http://www.vumc.nl

ROR https://ror.org/00q6h8f30

Funder(s)

Funder type University/education

Funder Name Vrije University Medical Centre (VUMC) (The Netherlands)

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