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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

Submission date
20/12/2005

Recruitment status
No longer recruiting

Registration date
20/12/2005

Overall study status
Completed

Last Edited
15/08/2008

Condition category
Haematological Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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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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
1. Number of required blood transfusions
2. 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

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

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)

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