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Randomised controlled study of iron supplementation to support the response to recombinant human erythropoietin for the treatment of chemotherapy-induced anaemia

Submission date
17/11/2006

Recruitment status
Stopped

Registration date
04/05/2007

Overall study status
Stopped

Last Edited
07/08/2009

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

NCT00482716

Secondary identifying numbers
Version 2 (Oct 2006)

Study information

Scientific Title

Acronym
High Iron Study

Study objectives
Parental iron will optimise the response to recombinant erythropoietin therapy in patients who are iron replete.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the East London and the City Research Ethics Committee on the 17th October 2006 (ref: 06/Q0605/93).

Study design
Randomised, controlled, open label, prospective 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
Chemotherapy induced anaemia

Interventions
As of 07/08/2009 the status of this record was updated to read: 'STOPPED', as this trial terminated early due to poor patient recruitment. The initial anticipated end date was 01/11 /2007 but this was extended after the lack of recruitment.

Eighty patients will be treated and randomised to receive either epoietin or epoietin plus 200 mg intravenous iron sucrose (Venefor) weekly for ten weeks or until a haemoglobin (Hb) of 13 g /dl is achieved (whichever is first). Any patient requiring blood transfusion while on the study will be considered to have completed the study at the time of the transfusion. Patients will be followed until the Hb reaches 13 g or until the end of the study period. Haemoglobin levels will be measured weekly.

Other blood tests include:
Baseline: zinc protoporphyrin (ZPP), reticulocyte haemoglobin content (CHR), transferrin saturation (TSAT), full blood count (FBC), ferritin, reticulocytes (Retic), vitamin B12, red cell folate, soluble transferrin receptor (sTFR), serum erythropoietin (EPO)
Week one: FBC, CHR, retic
Week four, eight and 12: as per baseline (without B12 and red cell folate)

Intervention Type
Supplement

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Iron supplementation (Venefor), epoietin

Primary outcome measure
The primary outcome will be the maximum haemoglobin achieved during the conduct of the study.

Secondary outcome measures
The secondary outcome will be the time to zenith haemoglobin or the achievement of a haemoglobin level of more than 13 g. All side effects will be recorded and graded although none are anticipated. A further stratification will be responsive, stable or progressive disease.

Overall study start date
01/11/2006

Completion date
24/04/2009

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. Any patients with a haemoglobin of less than or equal to 10.5 g/dl who is going to receive at least six more weeks of chemotherapy for any non-myeloid malignancy
2. Any patients with a percent saturation of transferrin more than or equal to 20% and a serum ferritin between 225 and 2250 pmol/L. Confirmatory data will include a reticulocyte

haemoglobin content (CHR) more than 31 and zinc protoporphyrin (ZPP) less than 80
3. Patients must be able to understand and signed written informed consent
4. An Eastern Cooperative Oncology Group (ECOG) performance status of zero to two

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Eighty patients

Key exclusion criteria
1. Patients with an anaemia of origin other than cancer or cancer chemotherapy
2. Prior intravenous (IV) iron therapy
3. Expectation of actual transfusion requirement during the course of the study. A transfusion given after randomisation wil be a study endpoint for that patient.
4. Allergy or intolerance to recombinant erythropoietin
5. Uncontrolled hypertension
6. Active infection
7. Primary bone marrow malignancies except for multiple myeloma, chronic lymphocytic leukaemia and indolent non Hogkin's lymphoma, where erythropoiesis-stimulating agents (ESA) therapy has been proven to be beneficial

Date of first enrolment
01/11/2006

Date of final enrolment
24/04/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Barts and the London NHS Trust
London
United Kingdom
EC1A 7BE

Sponsor information

Organisation
Barts and the London NHS Trust (UK)

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Research and Development Department
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Sponsor type
Hospital/treatment centre

Website
http://www.bartsandthelondon.org.uk/

ROR
https://ror.org/00b31g692

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
St. Bartholomew's Hospital (UK) - internal funding

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