

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 04/05/2007	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 07/08/2009	Condition category Haematological Disorders	<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

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 will 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 Hodgkin'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)

Sponsor details

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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