

Randomised controlled trial of maintaining low serum ferritin levels in patients receiving darbepoetin (Aranesp®)

Submission date 12/09/2003	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 12/09/2003	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 16/08/2012	Condition category Surgery	☐ 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

Protocol serial number
N0436121433

Study information

Scientific Title

Study objectives

Haemodialysis patients are currently treated with intravenous iron and subcutaneous recombinant human erythropoietin to treat anaemia associated with end-stage renal failure. To ensure optimum erythropoiesis, iron stores, as judged by serum ferritin, are kept above the normal range. Recently, a novel form of modified erythropoietin, darbopoetin alfa (Aranesp®), has been licensed for use. This has a longer duration of action and needs to be administered only once a week. Consequently, it does not result in a burst of erythropoietic activity. It is assumed that the prolonged erythropoiesis does not result in peaks of iron utilisation, and so requires lower levels of available iron, which can be replenished from iron stores sufficiently rapidly to continue to support erythropoiesis. We propose to study the effect of maintaining "normal" ferritin levels compared with "supranormal" ferritin in stable haemodialysis patients receiving Aranesp®.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Haemodialysis

Interventions

Randomised controlled trial. Random allocation to:

1. Maintenance of normal ferritin
2. Maintenance of elevated ferritin (standard therapy)

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Darbepoetin (Aranesp®)

Primary outcome(s)

Haemoglobin (g/dl), Darbepoetin (ug/kg/week), Serum Ferritin, Iron Dose (mg/kg/week). Transferrin saturation percentage. C-reactive protein.

Key secondary outcome(s)

Not provided at time of registration

Completion date

30/11/2003

Eligibility

Key inclusion criteria

Patients will be drawn from the population of haemodialysis patients attending Leeds General Infirmary renal unit.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/11/2002

Date of final enrolment

30/11/2003

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Renal and Liver Services

Leeds

United Kingdom

LS1 3EX

Sponsor information

Organisation

Department of Health (UK)

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

Leeds Teaching Hospitals NHS Trust (UK)

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration