ISRCTN89787518 https://doi.org/10.1186/ISRCTN89787518

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

Study design
Randomised controlled trial

Primary study design
Interventional

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