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 [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 16/08/2012	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr R Dedi

Contact details
Renal and Liver Services
St James's University Hospital
Beckett Street
Leeds
United Kingdom
LS1 3EX
+44 (0)113 243 3144

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/11/2002

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration

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
England

United Kingdom

Study participating centre
Renal and Liver Services
Leeds
United Kingdom
LS1 3EX

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Leeds Teaching Hospitals NHS Trust (UK)

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