

Is functional iron deficiency the cause of anaemia in haemodialysis patients with dialysis catheters? A randomised controlled study

Submission date

12/09/2003

Recruitment status

No longer recruiting

Registration date

12/09/2003

Overall study status

Completed

Last Edited

26/01/2016

Condition category

Nutritional, Metabolic, Endocrine

☐ 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

Contact name

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Additional identifiers

Protocol serial number

N0436121434

Study information

Scientific Title

Is functional iron deficiency the cause of anaemia in haemodialysis patients with dialysis catheters? A randomised controlled study

Study objectives

To confirm the presence of functional iron deficiency in iron replete haemodialysis patients with dialysis catheters.

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)

Not Specified

Health condition(s) or problem(s) studied

Haemodialysis

Interventions

Randomised controlled trial. Random allocation to:

1. Treatment one
2. Treatment two

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

1. To determine the relationship between functional iron deficiency and EPO resistance.
2. Serum ferritin
3. iron
4. transferrin saturation
5. percentage of hypochromic erythrocytes
6. haematocrit
7. reticulocyte count
8. reticulocyte haemoglobin concentration
9. serum C-r

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/10/2003

Eligibility

Key inclusion criteria

1. Haemodialysis patients over 18 years of age on dialysis treatment for at least 3 months
2. Stable haemodialysis patients dialyzing with a central venous catheter on erythropoietin (EPO) therapy

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

01/10/2002

Date of final enrolment

01/10/2003

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Leeds General Infirmary

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