

Safety and efficacy study of high cut-off haemodialysis as a maintenance therapy for end stage renal failure

Submission date 20/07/2010	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 14/10/2010	Overall study status Completed	☐ Protocol
Last Edited 19/09/2016	Condition category Urological and Genital Diseases	☐ 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

Dr Paul Cockwell

Contact details

University Hospital Birmingham
Metchley lane
Birmingham
United Kingdom
B152TH

-

paul.cockwell@uhb.nhs.uk

Additional identifiers

Protocol serial number

1.0

Study information

Scientific Title

Safety and efficacy study of high cut-off haemodialysis as a maintenance therapy for end stage renal failure: a randomised crossover trial

Study objectives

The increased removal of middle molecules and protein bound toxins by high cut-off haemodialysis will reduce inflammation in chronic dialysis patients.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Leicestershire, Northamptonshire and Rutland Research Ethics Committee 2, ref: 10/H0402/31

Study design

Randomised active-controlled crossover group trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

End stage renal failure, haemodialysis

Interventions

High cut-off dialysis

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Safety as defined by the maintenance of serum albumin.

Key secondary outcome(s)

1. Kinetics of removal of uraemic toxins (middle molecules and protein bound toxins) and the corresponding sustained reductions seen with the different dialysis schedules evaluated.
2. Dialysis dose
3. Quality of life
4. Thrombosis
5. Pulse wave velocity

Completion date

31/01/2011

Eligibility

Key inclusion criteria

1. Functioning AV-fistula
2. Between the ages of 18 and 80 years
3. End Stage Renal Failure (ESRF) undergoing regular haemodialysis (for > 3 months)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Terminal illness
2. Dialysis catheter in-situ
3. History of recurrent/poorly controlled infections
4. Inflammatory disease
5. Immunosuppressants
6. Cardiac or respiratory failure

Date of first enrolment

25/07/2010

Date of final enrolment

31/01/2011

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

University Hospital Birmingham

Birmingham

United Kingdom

B152TH

Sponsor information

Organisation

University Hospitals Birmingham NHS Foundation Trust (UK)

ROR

<https://ror.org/014ja3n03>

Funder(s)

Funder type

Industry

Funder Name

Gambro AB (Sweden) - Disposables are provided free of charge

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No