ISRCTN06015076 https://doi.org/10.1186/ISRCTN06015076

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

Submission date	Recruitment status	[ ] Prospectively registered
20/07/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
14/10/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
19/09/2016	Urological and Genital Diseases	[ ] 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
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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes