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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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a patient information sheet

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 measure
Safety as defined by the maintenance of serum albumin.

Secondary outcome measures
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

Overall study start date
25/07/2010

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
45

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
England

United Kingdom

Study participating centre
University Hospital Birmingham
Birmingham
United Kingdom
B152TH

Sponsor information

Organisation
University Hospitals Birmingham NHS Foundation Trust (UK)

Sponsor details
Metchley Lane
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chirs.counsell@uhb.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.uhb.nhs.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

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

Study outputs

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