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A randomised controlled crossover trial of biofeedback control of end-dialysis plasma conductivity versus progressive reduction of dialysate conductivity.

Submission date
30/09/2005

Recruitment status
No longer recruiting

Registration date
30/09/2005

Overall study status
Completed

Last Edited
21/04/2011

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
N0077135300

Study information

Scientific Title

Study objectives
Does Diacontrol improve haemodynamic stability in comparison with fixed dialysate sodium achieving identical end-dialysis plasma conductivity?

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)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Urological and Genital Diseases: Renal

Interventions
We propose to randomise patients to serial reduction of fixed dialysate conductivity or to reduction of end-dialysis plasma conductivity achieved using a biofeedback loop (Diacontrol). Diacontrol monitors plasma conductivity and adjusts dialysate conductivity to achieve a prescribed end-dialysis plasma conductivity. This should deliver a specific end-dialysis total body sodium, thus automatically adjusting for variation in interdialytic kietary sodium intake. Haemodynamic stability on dialysis should be improved with this technique, allowing more patients to reap the benefits of low dialysate conductivity.
Two groups of patients will have either Diacontrol or fixed dialysate conductivity. After serial reduction, the groups will cross over to the other modality. At the end of the trial all patients will revert to the unit standard dialysate of 13.6 mS/cm.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. End-dialysis plasma conductivity
2. Numbers of patients achieving each reduction
3. Haemodynamic stability, assessed using a variety of measures

Secondary outcome measures
Not provided at time of registration

Overall study start date
18/12/2003

Completion date
18/05/2004

Eligibility

Key inclusion criteria
Chronic haemodialysis patients

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
32

Key exclusion criteria
1. > 2 episodes of hypotension/week on current dialysis
2. On HDF

Date of first enrolment
18/12/2003

Date of final enrolment
18/05/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Derby Hospitals NHS Foundation Trust
Derby
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Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
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SW1A 2NL
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Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Derby Hospitals NHS Foundation Trust (UK), NHS R&D Support Funding

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?
Results article	results	01/03/2007		Yes	No