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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

Contact name
Dr Chris W McIntyre

Contact details
Derby Hospitals NHS Foundation Trust
Department of Nephrology
Derby City General Hospital
Uttoxeter Road
Derby
United Kingdom
DE22 3NE

Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Not Specified

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(s)
1. End-dialysis plasma conductivity
2. Numbers of patients achieving each reduction
3. Haemodynamic stability, assessed using a variety of measures

Key secondary outcome(s)
Not provided at time of registration

Completion date
18/05/2004

Eligibility

Key inclusion criteria
Chronic haemodialysis patients

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

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
United Kingdom

England

Study participating centre
Derby Hospitals NHS Foundation Trust
Derby
United Kingdom
DE22 3NE

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Government

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

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?
Results article	results	01/03/2007		Yes	No