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Study into achievement of isonatric haemodialysis by individual tailoring of dialysate sodium according to ionic mass balance derived from online conductance monitoring

Submission date	Recruitment status	[_] Prospectively registered
30/09/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/09/2005	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
16/04/2015	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
N0077114320

Study information

Scientific Title
Study into achievement of isonatric haemodialysis by individual tailoring of dialysate sodium according to ionic mass balance derived from online conductance monitoring

Study objectives
Whether or not individualising dialysate sodium has beneficial effects on haemodialysis patients interdialytic weight gains, blood pressure and thirst when compared to standard dialysate sodium.

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)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Interventions
The two groups will both undergo a 1-week period of initial data collection while being maintained on routine dialysis. Dialysis will be performed using a default dialysate sodium of 140 mmol/l.
The first group will then continue to dialyse against a standard dialysate sodium concentration of 140 mmol/l, while the second group undergoes a period of 1 month of sequential reduction of dialysate sodium according to online conductivity monitoring, aiming for isonatric dialysis (i.e. Ionic mass balance of 0-100 mmol of sodium). This will then be maintained for a period of one

month.
After that time, there will be a crossover period of adjustment, during which the first group will have their dialysate sodium tailored to their requirements, and the second group will revert in a gradual manner to a dialysate sodium of 140 mmol/l.
Again the two groups will be maintained for a further month, before both groups revert to a standard dialysate sodium at the end of the study.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Neutral sodium balance as assessed by ionic mass balance reduction in interdialytic weight gain.

Secondary outcome measures
Pre and post dialysis blood pressure, number of anti-hypertensive agents stability on dialysis, thirst score.

Overall study start date
23/09/2002

Completion date
23/03/2004

Eligibility

Key inclusion criteria
Patients on routine haemodialysis

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
We plan to enrol 60 - 100 patients currently established on haemodialysis.

Key exclusion criteria
No documented exclusion criteria. Protocol specifies ALL patients on established haemodialysis.

Date of first enrolment
23/09/2002

Date of final enrolment

23/03/2004

Locations

Countries of recruitment
England

United Kingdom

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

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
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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