ISRCTN71215609 https://doi.org/10.1186/ISRCTN71215609

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

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
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

Study type(s)
Treatment

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(s)
Neutral sodium balance as assessed by ionic mass balance reduction in interdialytic weight gain.

Key secondary outcome(s))
Pre and post dialysis blood pressure, number of anti-hypertensive agents stability on dialysis, thirst score.

Completion date
23/03/2004

Eligibility

Key inclusion criteria
Patients on routine haemodialysis

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

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
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