

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

Submission date 30/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 30/09/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 16/04/2015	Condition category Urological and Genital Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

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

79 Whitehall

London

United Kingdom

SW1A 2NL

+44 (0)20 7307 2622

dhmail@doh.gsi.org.uk

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