ISRCTN14411549 https://doi.org/10.1186/ISRCTN14411549

Effect of dialystate sodium concentration on intracellular and extracellular fluid volumes in regular chronic haemodialysis (HD) patients

Submission date	Recruitment status	[X] Prospectively registered
28/09/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
28/09/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
07/09/2012	Urological and Genital Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N0256183912

Study information

Scientific Title

Study objectives
Does dialysate sodium concentration affect sodium balance during haemodialysis, by altering the amount of sodium available for diffusion?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added June 2008: approved by University College Hospital Ethics Committee

Primary study design
Interventional

Study design
Prospective cross over design

Study type(s)
Treatment

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

Interventions
Each patient will dialyse against three different dialysate sodium concentrations. The sequence will be randomised.

Until June 2008, trial dates were 01/04/2006 to 01/10/2007.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
dialystate sodium

Primary outcome(s)
Intracellular and extracellular fluid volume changes, effluent dialysate sodium, interdialytic weight grain, predialysis blood pressure, intradialytic blood pressure, intradialytic blood volume changes.

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

Completion date
31/08/2009

Eligibility

Key inclusion criteria
Added June 2008:
1. 18 years or older
2. Stable on dialysis
3. 3 x week HD patients
4. Able to provide informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Lower age limit
18 Years

Sex
Not Specified

Key exclusion criteria
Added June 2008:
1. Unable to provide informed consent
2. Unstable on dialysis
3. Dialysis frequency < or > 3 x per week

Date of first enrolment
01/03/2008

Date of final enrolment
31/08/2009

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Department of Nephrology / Transplantation
London
United Kingdom
NW3 2QG

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Funder(s)

Funder type
Government

Funder Name
The Royal Free Hampstead NHS Trust (UK)

Funder Name
Special Trustees

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	01/10/2010		Yes	No