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

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Prospective cross over design

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
Intracellular and extracellular fluid volume changes, effluent dialysate sodium, interdialytic weight grain, predialysis blood pressure, intradialytic blood pressure, intradialytic blood volume changes.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/03/2008

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

Age group
Not Specified

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
13 patients, study number reviewed by Dr Morris, statistician population sciences The Royal Free Hospital.

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
England

United Kingdom

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

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
London
United Kingdom
SW1A 2NL
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dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
The Royal Free Hampstead NHS Trust (UK)

Funder Name
Special Trustees

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2010		Yes	No