

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	<input checked="" type="checkbox"/> Prospectively registered
Registration date 28/09/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 07/09/2012	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

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

Study design

Prospective cross over design

Primary study design

Interventional

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 gain, 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