

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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 gain, 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

+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

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