

A randomised crossover study to determine the effect of glucose enriched dialysis fluid on post-dialysis cognitive function

Submission date 30/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 30/09/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 14/09/2017	Condition category Nervous System 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0436151094

Study information

Scientific Title

A randomised crossover study to determine the effect of glucose enriched dialysis fluid on post-dialysis cognitive function

Study objectives

We intend to use two simple tests before and after a haemodialysis (HD) session to see how commonly HD induces a degree of delirium. After our initial survey, we shall repeat the tests after introducing glucose enriched dialysis fluid to see if this reduces the number of people that have a deterioration of their score

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled crossover group 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

Nervous System Diseases: Cognition disorders

Interventions

Interviews; Before-after trial

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Mini mental state exam score
2. Clock face drawing test score

Secondary outcome measures

Not provided at time of registration

Overall study start date

14/06/2004

Completion date

14/08/2004

Eligibility

Key inclusion criteria

Patients undergoing haemodialysis on ward 50 at the LGI

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

Not provided at time of registration

Key exclusion criteria

1. Not being able to understand the questions of the mini-mental state of examination or the instructions for the clock drawing
2. Having visual impairment or physical disability that prevents accurate clock drawing

Date of first enrolment

14/06/2004

Date of final enrolment

14/08/2004

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Leeds General Infirmary
Renal and Liver Services
Leeds
United Kingdom
LS1 3EX

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

Leeds Teaching Hospitals NHS 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results	conference proceedings	01/07/2006		No	No