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

Submission date Recruitment status [] Prospectively registered 30/09/2005 No longer recruiting [] Protocol [] Statistical analysis plan Registration date Overall study status 30/09/2005 Completed [X] Results [] Individual participant data Last Edited Condition category 14/09/2017 Nervous System 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 N0436151094

Study information

Scientific Title

A randomised crossover study to determine the effect of glucose enriched dialysis fluid on postdialysis 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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

Not provided at time of registration

Completion date

14/08/2004

Eligibility

Key inclusion criteria

Patients undergoing haemodialysis on ward 50 at the LGI

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

United Kingdom

England

Study participating centre Leeds General Infirmary

Renal and Liver Services Leeds United Kingdom LS1 3EX

Sponsor information

Organisation

Department of Health

Funder(s)

Funder type

Government

Funder Name

Leeds Teaching Hospitals NHS Trust (UK) - NHS R&D Support Funding

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?
Abstract results	conference proceedings	01/07/2006		No	No