ISRCTN47648806 https://doi.org/10.1186/ISRCTN47648806

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

Registration date
30/09/2005

Overall study status
Completed

Last Edited
14/09/2017

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Mark Wright

Contact details
Renal and Liver Services
Great George Street
Leeds
United Kingdom
LS1 3EX
+44 (0)113 392 2933
mark.wright@leedsth.nhs.uk

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