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The effect of glucose added to dialysis fluid on blood pressure, blood glucose and quality of life in hemodialysis patients. A placebo controlled cross-over study

Submission date
27/12/2005

Recruitment status
No longer recruiting

Registration date
26/01/2006

Overall study status
Completed

Last Edited
25/09/2009

Condition category
Nutritional, Metabolic, Endocrine

[_] 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2003-01

Study information

Scientific Title

Acronym
Blood pressure and glucose in dialysis water

Study objectives
We wanted to test the hypotheses that blood pressure was lower, that the variability of blood pressure and blood glucose was reduced, and that quality of life was improved when glucose was added to the dialysis fluid

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the local medical ethics committee

Study design
Placebo-controlled unblinded cross-over study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Chronic renal failure

Interventions
Glucose versus placebo

The purpose of the study was to determine the effect of glucose added to the dialysis fluid on:
1. Blood pressure and variation in blood pressure
2. Blood glucose and variation in blood glucose
3. Quality of life in patients treated with chronic maintenance hemodialysis

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Blood pressure, blood glucose, quality of life

Secondary outcome measures
Blood pressure variability, blood glucose variability

Overall study start date
01/05/2003

Completion date
31/07/2004

Eligibility

Key inclusion criteria
Age more than 18 years, both men and women, and hemodialysis treatment for more than three months

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
55-60

Key exclusion criteria
1. Treatment with hemodiafiltration
2. Change to another dialysis modality
3. Renal transplantation
4. Alcohol abuse defined as more than 21 units a week for men and more than fourteen units a week for women
5. Unwillingness to participate

Date of first enrolment
01/05/2003

Date of final enrolment
31/07/2004

Locations

Countries of recruitment
Denmark

Study participating centre
Department of Medical Research
Holstebro
Denmark
7500

Sponsor information

Organisation
Holstebro Hospital (Denmark)

Sponsor details
Department of Medical Research
Holstebro Hospital
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+45 (0)99125704
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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Research organisation

Funder Name
Ringkjobing County (Denmark)

Funder Name

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	01/04/2006		Yes	No