

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	☐ Prospectively registered
Registration date 26/01/2006	Overall study status Completed	☐ Protocol
Last Edited 25/09/2009	Condition category Nutritional, Metabolic, Endocrine	☐ Statistical analysis plan
		☒ 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

Protocol serial number

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

Primary study design

Interventional

Study design

Placebo-controlled unblinded cross-over study

Study type(s)

Quality of life

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(s)

Blood pressure, blood glucose, quality of life

Key secondary outcome(s)

Blood pressure variability, blood glucose variability

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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)

Funder(s)

Funder type

Research organisation

Funder Name

Ringjobing County (Denmark)

Funder Name

Danish Society of Nephrology (Denmark)

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?
Results article	results	01/04/2006		Yes	No