A comparison between the effects of icodextrin and glucose 2.27% on plasma volume in peritoneal dialysis patients

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The primary hypothesis of the study is that the use of icodextrin leads to a reduction in extracellular volume compared to glucose 2.27%, but that the effects of icodextrin and glucose 2.27% on plasma will not differ.

Ethical review	Approved WMO
Status	Pending
Health condition type	Renal disorders (excl nephropathies)
Study type	Interventional

Summary

ID

NL-OMON30588

Source
ToetsingOnline

Brief title
icodextrin and plasmavolume

Condition

- Renal disorders (excl nephropathies)

Synonym
renal failure, renal insufficiency

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W,Baxter

Intervention

Keyword: icodextrin, peritoneal dialysis, plasma volume, salt and water removal

Outcome measures

Primary outcome

In this study the effects of glucose 2.27% and icodextrin 7.5% will be compared

for the long dwell on plasma volume, extracellular volume and blood pressure

control.

Secondary outcome

xx

Study description

Background summary

Peritoneal dialysis (PD) patients are mostly overhydrated. Overhydration could induce hypertension and increase the cardiac workload. In PD, ultrafiltration of bodywater occurs by dialysis fluids containing different concentrations of glucose. More ultrafiltration could be realised by using icodextrin, a dialysis fluid which contains polymers of glucose. Although use of icodextrin or glucose fluids is not different for blood pressure as expected, because of the better ultrafiltration capacity of icodextrin. In this study we will compare the effect of icodextrin in peritoneal dialysis with glucose-containing dialysis fluids. Especially regulation of the blood pressure and the distribution of the body water will be studied.

Study objective

The primary hypothesis of the study is that the use of icodextrin leads to a reduction in extracellular volume compared to glucose 2.27%, but that the effects of icodextrin and glucose 2.27% on plasma will not differ.

Study design

Patients will be studied according to a randomized cross-over design. The total duration of the study is 3 months. During a period of one month all patients are prescribed 2.27% glucose solutions for the long dwell. After the run-in

period patients will receive one-monthly treatment with icodextrin for the log dwell followed by one-monthly treatment with glucose 2.27% for the long dwell (A-B), or will start with glucose 2.27% and followed by icodextrin (B-A).

Intervention

Blood sampling
24-hours blood pressure monitoring
I-125 albumine method for assessment of plasma volume
Bromide dilution method for assessment of the extracellular volume
Multifrequency bioimpedance analysis for assessment of the total body water
Assessment of peritoneal ultrafiltration volume and sodium removal by 24-hours dialysate collection
Assessment of residual renal function by 24-hours urine collection

Study burden and risks

There are no other risks for the patients than known in peritoneal dialysis.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

clinical stable patients treated with peritoneal dialysis

Exclusion criteria

chronic heart failure NYHA III or higher
known hypersensitivity to icodextrin
pacemaker
pregnancy
younger than 18 years
inability to give informed consent
within one month of peritonitis
patients unable to stop icodextrin on clinical grounds

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL
Recruitment status: Pending
Start date (anticipated): 01-01-2007

Enrollment:	12
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	2.27% glucose
Generic name:	2.27% glucose
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	31-01-2007
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2006-006211-80-NL
CCMO	NL15242.068.07