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

Published: 31-01-2007
Last updated: 08-05-2024

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

**Public**
Academisch Ziekenhuis Maastricht

Postbus 5800
6202 AZ Maastricht
NL
**Scientific**
Academisch Ziekenhuis Maastricht

Postbus 5800
6202 AZ Maastricht
NL

# 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 |