Influence of the solution used for the long dwell on the results of the Peritoneal Equilibration Test using 3.86% glucose in CAPD.

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The aim of the present study is to compare the following transport characteristics for a modified 3.86% glucose PET preceded by a long (>8 hours) dwell with 3.86% glucose (PET A) and one preceded by a long dwell with 7.5% icodextrin (PET B), and...

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

Summary

ID

NL-OMON35502

Source
ToetsingOnline

Brief title
Ico-PET

Condition

- Renal disorders (excl nephropathies)

Synonym
peritoneal dialysis, peritoneal equilibration test

Research involving
Human

Sponsors and support

Primary sponsor: Interne Geneeskunde - Onderafdeling Nefrologie

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Icodextrin, PET, preceding dwell

Outcome measures

Primary outcome

The following parameters will be assessed:

- Standardized 3.86% glucose PET preceded by a night dwell (8 to 12 hours) with a 3.86% glucose solution

- Standardized 3.86% glucose PET preceded by a night dwell (8 to 12 hours) with glucose polymer solution (Icodextrin)

- Standardized 3.86% glucose PET preceded by a night dwell (8 to 12 hours) with a 2.27% glucose solution

The main outcome parameter will be D0/Dt of glucose. Do is the glucose concentration in the dialysate at start and Dt is the glucose concentration in the dialysate after 60 and 240 minutes.

Secondary outcome

The following laboratory parameters will be assessed:

- Serum: glucose, urea, creatinine, sodium, albumin

- Dialysate fluid: glucose, urea, creatinine, phosphate, sodium, albumin (of de preceding night dwell and during the PET at start, after 60 and 240 min)

Study description

Background summary

Membrane characteristics are of great importance for the success of peritoneal dialysis (PD). Every 6 months the transport properties of the peritoneal membrane are measured to characterize the functional status of the membrane by a peritoneal equilibration test (PET), both in terms of solute transport, and fluid removal (ultrafiltration). Point of concern has been the influence of the preceding dwell on the PET results. The last decade there is a growing use of the glucose polymer icodextrin as dialysis solution (by an estimated 50%). Since icodextrin induces ultrafiltration by colloid osmosis through the small pores of the peritoneal membrane, it is especially effective during long dwell times. In a previous study by Lilaj et al. the results of a PET, performed with 2.27% glucose after a preceding dwell (10 hours) with 1.36% glucose was compared with a 2.27% glucose PET after a preceding dwell (10 hours) with icodextrin. Significant differences were observed for D/P creatinine, phosphate and sodium, which were all greater after the icodextrin dwell. This could be explained by existence of a residual volume that still contained icodextrin and thereby could have lead to an additional convective transport of small solutes. As an alternative explanation the authors proposed that the different solutions might have different vasoactive effects on the peritoneal membrane, modulated by the release of cytokines. However, no differences in mass transport area coefficients (MTAC) of small solutes were reported.
Recently the ISPD has proposed to perform the PET with a 3.86% glucose solution in stead of 2.27% glucose solution as was done in the study by Lilaj et al. No information is available on the effect of the preceding night dwell on net ultrafiltration using the advised 3.86% glucose solution or icodextrin before the PET. Also the possible influence of the advised 3.86% glucose solution or icodextrin as preceding exchange on free water transport, estimated using the maximum dip in D/P sodium (sodium sieving) in the first phase of the dwell, has not been examined before. Hypertonic glucose concentrations could also influence the vascular reactivity and consequently decrease the difference in transport characteristics with icodextrin.
In this study, the influence of the preceding nightdwell (3.86% glucose solution = standard) on the results of the 3.86% PET will be compared to the influence of icodextrin as preceding night dwell and with 2.27% glucose solution (world wide most used as preceding dwell).
The practical consequence of this study is that, in case of equivalence between the dialysis solutions, patients who already use icodextrin for their standard treatment during nighttime, can continue this solution also in preparation for the PET, which will make the preparation phase easier for the patient.

Study objective

The aim of the present study is to compare the following transport characteristics for a modified 3.86% glucose PET preceded by a long (>8 hours) dwell with 3.86% glucose (PET A) and one preceded by a long dwell with 7.5%

icodextrin (PET B), and a third PET preceded with 2.27% glucose solution (PET C):
1. Small solute transport (including a characterization into a transport group)
2. Net ultrafiltration (= fluid removal)
3. Sodium sieving and free water transport

Study design

In 20 stable patients on CAPD we will perform two standardized 3.86% glucose PETs (duration 4 hours) in random order (with sealed envelopes) within 2 weeks. One test will be preceded by a preceding night dwell of 8 to 12 hours with a standarized 3.86% glucose solution (PET A). The other PETs will be performed after a preceding night dwell of 8 to 12 hours using a glucose polymer solution (icodextrin) (PET B) and 2.27% glucose solution (PET C).
In all tests characterization, small solute transport (D/P creatinine and urea, Dt/D0 glucose, MTACcreatinine and urea), sodium sieving (dip D/P sodium after 2 hours) with calculation of free water transport and net ultrafiltration will be achieved.

Intervention

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Study burden and risks

There are no risks for the patients. In this study patients will use another regularly used dialysate fluid (icodextrin or 2.27% glucose) in state of the 3.86% glucose solution as preceding night dwell before perfomance of the PET. Ultrafiltration (fluid removal) is basically not different between the standard procedure (3.86% gluoces solution) and icodextrin.
There are no direct benefits for the patients.

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

stable CAPD patients > 18 years old
peritonitis-free for at least 6 weeks before and between both PETs
able to give informent consent

Exclusion criteria

peritonitis less than 6 weeks before or between the PETs
Allergy of icodextrin

Study design

Design

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

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2009
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	19-10-2009
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO Date:	14-01-2010
Application type:	Amendment
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
CCMO	NL28726.068.09