Prevention of peritonitis in patients with peritoneal dialysis - effects of regular follow-up of patients* theoretical knowledge and practical skills with focus on infection prophylaxis

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To study if regular follow-up of PD patients with testing of their theoretical and practical knowledge (hereafter called *new type of follow-up*) can reduce the incidence of peritonitis, reduce the technique failure rate related to peritonitis, and...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hepatobiliary neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON38141

Source
ToetsingOnline

Brief title
Peritonitis Prevention Study (PEPS)

Condition

- Hepatobiliary neoplasms malignant and unspecified
- Renal disorders (excl nephropathies)

Synonym
peritonitis abdominal infection

Research involving
Human

Sponsors and support

Primary sponsor: Dianet, locatie AMC, Amsterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Chronic Kidney Failure, Peritoneal Dialysis, Peritonitis

Outcome measures

Primary outcome

To study if a new type of follow up of PD patients with regular testing of their theoretical and practical knowledge can prolong the time to first peritonitis an reduce the incidence of peritonitis compared to standard treatment.

Secondary outcome

To study risk factors for peritonitis, especially diabetes and age and if a new type of follow up can reduce the technique-failure rate related to peritonitis.

To study if a new type of follow up can reduce the time of hospitalisation related to peritonitis compared to standard treatment

Study description

Background summary

Peritonitis is a significant problem in peritoneal dialysis (PD). Some patients may suffer episodes of peritonitis often while others never get such an infection. The risk to suffer an episode of peritonitis is greater during the first year of PD treatment than later. It has been demonstrated that non-compliance with the PD protocol is an important risk factor for peritonitis. We therefore want to study if structured follow-up of PD patients* theoretical and practical knowledge with focus on infection prophylaxis can

reduce the incidence of peritonitis compared to a routine regimen.

Study objective

To study if regular follow-up of PD patients with testing of their theoretical and practical knowledge (hereafter called *new type of follow-up*) can reduce the incidence of peritonitis, reduce the technique failure rate related to peritonitis, and reduce the time of hospitalization related to peritonitis compared to a routine regimen.

Study design

The study is a randomized, multi-centre investigation of 750 new PD patients in Norway, Sweden, Denmark, Finland, Estonia, Latvia and Holland. It includes a follow-up group and a control group. The follow-up group will undergo regular testing of theoretical and practical knowledge regarding PD with focus on infection prophylaxis including retraining if needed. The control group will be treated according to the routines of the centre.

Intervention

1. The patient should fill in a questionnaire with theoretical and practical questions with focus on infection and infection prophylaxis during PD treatment.
Goal: At least 80% of the questions should be correct. If the goal is not reached, further training should be given until the goal is reached.

2. The patient will do a practical test including hand disinfection, PD exchange technique, exit-site care. Hand disinfection skills will be controlled with the help of fluorescent alcohol and a UV lamp.
Goal: All steps of the practical test should be correctly performed. If not, further training will be given until the goal is reached.

Study burden and risks

Time investment of 60-120 minutes per visit, with a total of 480-960 minutes during the 3 years follow-up. There are no risks associated with this study.

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

Able to perform peritoneal dialysis without assistance

Exclusion criteria

Previous PD-treatment less than 2 years ago
Peritonitis before inclusion
Active malignancy
Participation in other studies during the study period, which may affect the outcome of the present study.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-04-2012
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	18-05-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
ClinicalTrials.gov	NCT01293799
CCMO	NL35699.018.11