Surgical technique for continuous ambulant peritoneal dialysis catheter insertion: Laparoscopic or open catheter insertion?

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Primary Objective: Does the use of the laparoscopic insertion technique lower the incidence of malfunctioning CAPD-catheters at 6 weeks postoperatively? Secondary Objectives: Does the use of the laparoscopic insertion technique improve catheter…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Nephropathies
Study type	Interventional

Summary

ID

NL-OMON36494

Source
ToetsingOnline

Brief title
LOCI-trial

Condition

- Nephropathies
- Therapeutic procedures and supportive care NEC

Synonym
End stage renal disease

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: (mini)Laparotomy, Catheter, Laparoscopy, Peritoneal dialysis

Outcome measures

Primary outcome

The percentage of functioning CAPD catheters at 6 weeks postoperatively.

Secondary outcome

Catheter longevity, the rate of surgical complications, mortality, leakage,

catheter migration, re-admissions, infections and duration of hospital stay.

The quality of life and pain score. The use of postoperative pain medication.

The peritoneal membrane function.

Study description

Background summary

Almost 15.000 Dutch patients with end-stage renal disease (ESRD) are dependent of renal replacement therapy (RRT; dialysis and transplantation). Of the nearly 6300 patients on dialysis, one fifth is on continuous ambulant peritoneal dialysis (CAPD). It has an advantage over haemodialysis in that it allows patients greater freedom to perform daily activities; it also provides other clinical benefits, such as less dietary and fluid restriction, better blood pressure control and less cardiovascular stress. Another advantage of CAPD over haemodialysis is the costs. Annually, CAPD costs $43,000 dollars less than haemodialysis, therefore well-functioning CAPD has major economic consequences. The key to successful CAPD is the presence of a well-functioning dialysis catheter, defined as one that facilitates free dialysis solution inflow and outflow. However, we have noticed that CAPD catheter insertion has a high rate of technical failure using the standard open technique and thus needs improvement. The current literature describes a range from 10-35 % catheter failure with the open technique. Catheter malfunction is most commonly caused

by mechanical complications, such as kinking or malpositioning of the catheter tip. Complications frequently cause considerable problems for ESRD patients, including re-operation and an increased risk of losing access to CAPD. For a small but significant number of patients this leads to severe morbidity and even mortality. Laparoscopic procedures have proven to be superior to a number of open surgical procedures, by reducing morbidity, length of hospital stay, postoperative pain and lead to a quicker convalescence. In contrast to the open technique, laparoscopic insertion enables the surgeon to insert the CAPD-catheter under direct vision using a video-laparoscope, and thus enables him to ascertain the correct catheter position at the end of the operation. In current literature, comparative trials show no significant difference in the risk of catheter removal, replacement or technical failure between both techniques, however there are no well-designed randomized controlled trial comparing laparoscopic CAPD-catheter insertion to the traditional open technique.

Study objective

Primary Objective: Does the use of the laparoscopic insertion technique lower the incidence of malfunctioning CAPD-catheters at 6 weeks postoperatively? Secondary Objectives: Does the use of the laparoscopic insertion technique improve catheter longevity and reduce the rate of surgical complications, mortality, leakage, catheter migration, re-admissions, exit-site infections, peritonitis and duration of hospital stay? Does the use of the laparoscopic insertion technique reduce postoperative pain, the use of postoperative pain medication and increase the quality of life? Does laparoscopic catheter insertion influence peritoneal membrane function at 2 months postoperatively as measured with peritoneal equilibration test?

Study design

A multicenter prospective single blinded randomized controlled trial. Duration of the study will be 18 months.

Intervention

Group 1: Laparoscopic catheter insertion
Group 2: Open catheter insertion

Study burden and risks

The burden and risks associated with participation is limited to one of the two surgical techniques of CAPD-catheter placement. The number of blood samples, the number of site visits and physical examinations is the same as in the current standard protocol. One additional X-ray image of the abdomen will be done in all patients at day one and six months postoperatively. Abdominal x-ray

is necessary to identify catheter position or migration. Participants are asked to fill out a quality of life questionnaire before surgery and at week 4, 6, 8, 12 and 26 postoperatively. Participants are asked to give a pain score using the visual analogue scale at day 0, 1, 2, 3, 7 and 14 postoperatively and fill out the EuroQol questionnaire preoperatively and at day 3 and week 1, 2, 4, 12, 26.

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

All end stage renal disease patients with an indication for continuous ambulant peritoneal dialysis. Minimum age is 18 years.

Exclusion criteria

Body Mass Index greater than 35 kg/m2. Patients with severe COPD (or patients otherwise not able to withstand a laparoscopic procedure). Patients younger than 18 years. Mental retardation.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-05-2011
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	22-04-2011
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	13-02-2012
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam

(Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 20701
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL34769.078.11
OMON	NL-OMON20701