Inbrengen van continue ambulante peritoneaal dialyse catheters: Kijkoperatie of open techniek?

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20701

Source
Nationaal Trial Register

Brief title
LOCI-trial

Health condition

End-stage renal disease
Peritoneal dialysis
Laparoscopy
Open

Sponsors and support

Primary sponsor: Erasmus Medical Center, Rotterdam
Source(s) of monetary or material Support: Erasmus Medical Center, Rotterdam

Intervention

Outcome measures

Primary outcome

Percentage of functioning catheters at 6 weeks postoperatively.

Secondary outcome

1. Surgical complications;

2. PD complications;

3. Pain score;

4. Quality of Life;

5. Cost-effectiveness;

6. Catheter survival.

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

The use of the laparoscopic insertion technique will lower the proportion of malfunctioning PD-catheters.

Study design

1. Baseline;

2. 6 weeks;

3. 6 months.

Intervention

1. Laparoscopic PD catheter insertion;

2. Open PD catheter insertion.

Contacts

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Eligibility criteria

Inclusion criteria

1. All patients with an indication for peritoneal dialysis;

2. 18 years and older.

Exclusion criteria

1. BMI >35 kg/m2;

2. Severe COPD (or otherwise not able to withstand laparoscopic surgery);

3. Age <18 years.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-05-2011
Enrollment:	100
Type:	Anticipated

Ethics review

Positive opinion

Date:	30-04-2011

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 36494
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL2740
NTR-old	NTR2878
CCMO	NL34769.078.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON36494

Study results

Summary results
N/A