

Laparoscopic Peritoneal Dialysis Catheter Placement: with or without omental and catheter fixation

Published: 04-09-2019

Last updated: 03-06-2024

Comparison of functional outcome of PD catheters in the two placement techniques. Describing 30 day mortality and short and middle term complications.

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

Summary

ID

NL-OMON54822

Source

ToetsingOnline

Brief title

CAPD II trial

Condition

- Other condition
- Nephropathies
- Vascular therapeutic procedures

Synonym

peritoneal dialysis, Renal failure

Health condition

nierfunctie stoornissen waarvoor peritoneaal dialyse

Research involving

Human

Sponsors and support

Primary sponsor: Vaatchirurgie

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

Intervention

Keyword: catheter, fixation, laparoscopic, peritoneal dialysis

Outcome measures

Primary outcome

Functional outcome of the PD catheter.

Secondary outcome

30 day mortality

Short and middle term complications

Study description

Background summary

The patient population with end-stage renal disease dependent on dialysis is increasing. This renal replacement therapy can be haemodialysis or peritoneal dialysis. Both options have selected indications. The present study focusses on patients starting peritoneal dialysis. To facilitate this technique, a catheter has to be placed in the peritoneal cavity to facilitate unobstructed in- and outflow of dialysate multiple times a day. An adequate functioning catheter is essential. Several infectious and non-infectious complications can hamper peritoneal dialysis. Obstruction and dislocation of the catheter are described to be influenced by surgical placement technique. There are different methods of catheter placement but nowadays laparoscopic placement is preferred. From previous research as the CAPD I trial we know that g=failure rates up to 30 % are seen.

In literature, beneficial outcome is seen with advanced laparoscopic techniques and fixation of catheter and omentum.

No randomised trial comparing laparoscopic techniques with advanced laparoscopy have been described so far. This trial will compare the functional outcome of the PD catheter in both techniques and describe short and median term complications.

Study objective

Comparison of functional outcome of PD catheters in the two placement techniques.

Describing 30 day mortality and short and middle term complications.

Study design

Multicenter randomized controlled clinical trial.

Intervention

Laparoscopic PD catheter placement versus laparoscopic catheter placement with fixation of catheter and omentum. Both treatment options are part of regular patient care.

Study burden and risks

The burden for the patient is not different in the study than in standard care.

Both surgical techniques are performed by experienced surgeons. The techniques are already routinely performed.

Hospital admission and follow up are the same.

Contacts

Public

Selecteer

P. DeByelaan 25
Maastricht 6229 HX
NL

Scientific

Selecteer

P. DeByelaan 25
Maastricht 6229 HX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Inclusion criteria

- Age \geq 18 years old
- End stage renal disease
- Suitable for CAPD catheter placement by laparoscopic technique
- Informed consent

Exclusion criteria

- No informed consent
- Malignancies
- Other intervention during the same surgical procedure not related to PD placement in the abdominal cavity
- Loss of peritoneal function

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 17-01-2020

Enrollment:	70
Type:	Actual

Ethics review

Approved WMO	
Date:	04-09-2019
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
Other	28868
CCMO	NL66424.068.18

Study results

Date completed:	01-03-2024
Actual enrolment:	76