Open vs Laparoscopic CAPD catheter placement, a randomized controlled clinical trial

Published: 24-11-2009
Last updated: 15-05-2024

Primary Objective:Determination of the best surgical approach in the individual patient to achieve optimal outcome statistics (catheter survival, 30-day or in-hospital mortality and long-term mortality) Secondary Objective:Comparison of short and...

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

Summary

ID

NL-OMON32970

Source
ToetsingOnline

Brief title
CAPD Trial

Condition

- Other condition
- Nephropathies
- Vascular therapeutic procedures

Synonym
Renal failure peritoneal dialysis

Health condition

Nierfunctiestoornis waarvoor CAPD

Research involving

Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Catheter, Laparoscopic procedure, Open procedure, Peritoneal dialysis

Outcome measures

Primary outcome

1) Catheter survival: Number of patients with proper functioning catheter

o After three months

o After six months

o After 1 year

2) 30-day or in-hospital mortality and long-term mortality

Secondary outcome

1) Number of short and long-term post-operative complications

Short term complications:

Bowel perforation, bleeding, wound infection, early peritonitis,

malposition, outflow failure, dialysate leakage

Long term complications:

Exit site infection, tunnel infection, cuff protrusion, malposition,

outflow failure, dialysate leakage, hernias,

peritonitis

2) Patency of CAPD catheter

* Primary patency (without interventions)

* Primary assisted patency (with use of antibiotics)

* Secondary patency (need for additional intervention)

Study description

Background summary

The patient population with end-stage renal disease dependent on dialysis is increasing. This renal replacement therapy can take place in two different ways: haemodialysis and peritoneal dialysis. Boths options have their patient population in which a certain technique is more suitable. The present study focusses on patients who will become dependent on peritoneal dialysis. To facilitate this technique, a catheter has to be placed in the peritoneal cavity in order to administer the dialsysate which has to be changed severel times a day. A well-functioning catheter is of the utmost importance for the success of this therapy. Several catheter complications, both infectious and non-infectious, hamper the CAPD treatment. The infectious complications can be subdivided into peritonitis, exit site infections and tunnel infections whereas non-infectious complications can be subdivided into abdominal hernia, dialysis leakage, obstruction of the catheter, adhesions in the peritoneal cavity and catheter tip migration.
Clinical practivce reveals two different techniques by which the abdominal catheter can be placed; the open procedure and the laparoscopic procedure. Untill now, there is no agreement which technique results in more complications and interventions and thus which technique has the potency to result in the most optimal catheter functioning.

Study objective

Primary Objective:
Determination of the best surgical approach in the individual patient to achieve optimal outcome statistics (catheter survival, 30-day or in-hospital mortality and long-term mortality)

Secondary Objective:
Comparison of short and long-term complications in patients who receive a catheter for peritoneal dialysis by either open surgery or laparoscopic surgery.

Study design

Multicenter randomized controlled clinical trial

Patients will be asked to participate in this study after screening for in- and exclusion criteria by the surgeon. After the informed consent procedure patients of both centers will be randomized by computer in either the laparoscopic or the open surgical arm. During follow-up of the patient, infectious and non-infectious complications will be monitored and overall usability of the catheter will be evaluated.

Intervention

Placement of a CAPD catheter either by an open or laparoscopic surgical procedure. Both treatment options are part of regular patient care. Description of the surgical procedure is available on page 9,10 and 11 in the study protocol.

Study burden and risks

The burden on the patient doesn't change compared to current clinical practice. The indication for the intervention will be set during a visit to the pre-dialysis clinic by independant physisians. After this the patient will be referred to the surgical out-patient clinic where the informed consent procedure takes place. The patient is informed about the surgical procedures and after informed consent the patient is randomised by computer in either the open or the laparoscopic arm.
The surgeon is well trained and experienced in performing both procedures. The follow-up of the patients will take place during regular follow-up on the dialysis ward and thus extra visits to the clinic will not be necessairy.

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

Age between 18-85
Randomisation by computer
Suitable for both CAPD catheter and intervention strategies
Informed consent

Exclusion criteria

Life expectancy < 1 year
Other intervention during the same surgical procedure
Loss of peritoneal function
No informed consent

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):	29-03-2010
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO

Date:	24-11-2009
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

ID: 24948
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL28836.068.09
Other	Pending
OMON	NL-OMON24948