

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

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

**Ethische beoordeling** Positief advies

**Status** Werving gestart

**Type aandoening** -

**Onderzoekstype** Interventie onderzoek

## Samenvatting

### ID

NL-OMON20701

### Bron

Nationaal Trial Register

### Verkorte titel

LOCI-trial

### Aandoening

End-stage renal disease

Peritoneal dialysis

Laparoscopy

Open

### Ondersteuning

**Primaire sponsor:** Erasmus Medical Center, Rotterdam

**Overige ondersteuning:** Erasmus Medical Center, Rotterdam

### Onderzoeksproduct en/of interventie

## **Uitkomstmaten**

### **Primaire uitkomstmaten**

Percentage of functioning catheters at 6 weeks postoperatively.

## **Toelichting onderzoek**

### **Achtergrond van het onderzoek**

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.

### **Doel van het onderzoek**

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

### **Onderzoeksopzet**

1. Baseline;
2. 6 weeks;
3. 6 months.

### **Onderzoeksproduct en/of interventie**

1. Laparoscopic PD catheter insertion;
2. Open PD catheter insertion.

## **Contactpersonen**

### **Publiek**

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### **Wetenschappelijk**

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## **Deelname eisen**

### **Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)**

1. All patients with an indication for peritoneal dialysis;
2. 18 years and older.

## **Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)**

1. BMI >35 kg/m<sup>2</sup>;
2. Severe COPD (or otherwise not able to withstand laparoscopic surgery);
3. Age <18 years.

## **Onderzoeksopzet**

### **Opzet**

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Enkelblind
Controle:	Actieve controle groep

### **Deelname**

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	16-05-2011
Aantal proefpersonen:	100
Type:	Verwachte startdatum

## **Ethische beoordeling**

Positief advies	
Datum:	30-04-2011
Soort:	Eerste indiening

## **Registraties**

## **Opgevolgd door onderstaande (mogelijk meer actuele) registratie**

ID: 36494

Bron: ToetsingOnline

Titel:

## **Andere (mogelijk minder actuele) registraties in dit register**

Geen registraties gevonden.

## **In overige registers**

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

## **Resultaten**

### **Samenvatting resultaten**

N/A