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

Gepubliceerd: 30-04-2011 Laatst bijgewerkt: 15-05-2024

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
NTR

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

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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/m2;

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

3. Age <18 years.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

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

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

Resultaten

Samenvatting resultaten
N/A