Early innovative Closure of Leaking low colorEctal ANastomoses; a multicenter study.

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Due to an expected increase in colorectal cancer there will be a subsequent increase in Low Anterior Resections (LAR). Anastomotic leakage can occur in up to 11% of the patients after a LAR for colorectal carcinomas. Leakage interferes with stoma…

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON28725

Bron
NTR

Verkorte titel
CLEAN-study

Aandoening

All patients that are older then 18 years who have an insufficient anastomosis within 5 cm from the upper border of the anal canal are eligible.

Ondersteuning

Primaire sponsor: AMC

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary outcome parameters are the number of ostomies successfully closed within 3 months. Success is be defined as normal defecation after stoma closure without signs of sepsis 3 months after closure.

Toelichting onderzoek

Doel van het onderzoek

Due to an expected increase in colorectal cancer there will be a subsequent increase in Low Anterior Resections (LAR). Anastomotic leakage can occur in up to 11% of the patients after a LAR for colorectal carcinomas. Leakage interferes with stoma reversal, might compromise pouch function later on, and might result in a chronic presacral sinus precluding defect closure. A relative new technique for the treatment of anastomotic leakage is endosponge® treatment. However the traditional endosponge® treatment is associated with high material costs and a long duration of treatment. Therefore a complete new technique was developed. The early closure of the anastomotic dehiscense after endosponge® therapy might overcome these drawbacks and reduce the costs, improve the neorectum function, quality of life and improve ileostomy reversal.

Onderzoeksopzet

3, 6, 9 and 12 months

Onderzoeksproduct en/of interventie

As soon as the anastomotic insufficiency is diagnosed, the anastomosis is defunctioned if not done so primarily. If the CT scan shows extravasation of enteral contrast in a presacral cavity, the patient is sent to the department of Gastroenterology of one of the three intervention centers to have an endoscopy to evaluate the level of anastomosis, the size of the defect and the size of the presacral cavity. In day care one or more Endosponges® are placed in the presacral cavity in order to clean the cavity prior to closure of the anastomotic defect. The treatment is continued until the cavity is clean. Within 7 – 14 days after initiation of Endosponge® treatment, the anastomotic gap is attempted to close with interrupted sutures under general anesthetics. If not succesfull, Endosponge® treatment is continued until closure of the cavity.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Anastomotic leakage after LAR (max 5 cm of the anus).

2. Confirmed anastomotic leakage on CT-scan or endoscopy.

3. Deviated ileostoma in situ before the start of endo-sponge treatment.

4. Maximal time interval of 6 weeks between the operation and the start of the endo-sponge treatment.

5. Age > 18 years and mental competent.

6. Abscess cavity is accessible by endoscopy.

7. Patient can be followed for 2 years.

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

1. Female patient with an ventrally located anastomotic defect

2. Signs of sepsis for which treatment is mandatory, i.e. ICU admittance

3. Steroids of more than 20 mg/day

4. Anastomotic leakage in the medical history

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	05-07-2013
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4495
NTR-old	NTR4671
Ander register	:

Resultaten