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

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28725

Source
NTR

Brief title
CLEAN-study

Health condition

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.

Sponsors and support

Primary sponsor: AMC

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

Secondary parameters are number of anastomotic defects closed within 2-3 weeks, time to closure of the defunctioning ostomy, quality of life, costs, functional outcome after closure, duration of endosponge treatment an the need for surgical re-intervention for each closure technique.

Study description

Study objective

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.

Study design

3, 6, 9 and 12 months

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-07-2013
Enrollment:	30
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL4495
NTR-old	NTR4671
Other	:

Study results