Prevention of anastomotic leakage in colorectal surgery with a biodegradable drain.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27437

Source
NTR

Brief title
C-Seal

Health condition

Colorectal Surgery Anastomotic Leakage C-Seal Drain

Sponsors and support

Primary sponsor: UMC Groningen, Dept. of Surgery
Source(s) of monetary or material Support: UMC Groningen

Intervention

Outcome measures

Primary outcome

The primary endpoint is the incidence of anastomotic leakage leading to invasive treatment within 30 days after the primary operation.

1. Anastomotic leakage is defined as a communication between the intra- and extraluminal compartments owing to a defect of the integrity of the intestinal wall at the anastomosis;

2. An abscess in the proximity of the anastomosis is considered as AL;

3. Invasive treatment is defined as any invasive procedure after the primary operation: Surgical treatment in the operating theatre or radiological drainage.

Secondary outcome

1. Number of dismantled anastomoses;

2. Grade A, B or C AL within 30 days after the primary operation;

3. The interval between the primary operation and the diagnosis of AL;

4. Pain score at day 3 postoperatively on a Visual Analogue Scale;

5. The number of ostomies created;

6. Late anastomotic leakage (diagnosed ≥30 days and within 1 year postoperative);

7. The number of ostomies present after one year;

8. The total duration of hospital stay including readmissions for (serious) adverse events and/or stoma closure;

9. The interval between the primary operation and the excretion of the C-seal through the anus;

10. Interval between C-seal application and C-seal loss;

11. Other complications.

Study description

Background summary

The most important complication and cause of death following low anterior resection (LAR) of the rectum is anastomotic leakage (5-20%). In many cases, re-interventions are needed with creation of a stoma and/or drainage of an abscess. To avoid serious complications like peritonitis and septic shock it is important to prevent the occurrence of anastomotic leakage. Furthermore there is an increasing use of preoperative radiotherapy in rectal cancer which may cause additional problems in anastomotic healing.

Since the introduction of circular staplers in 1975, stapled low colorectal anastomoses became routinely feasible. Stapled colorectal anastomoses have been widely accepted as the standard approach to restore continuity after colorectal resection.

The C-seal is a biodegradable thin-walled drain. It is compatible with the circular stapler used in almost all LARs. It is developed to prevent extravasation of intracolonic content to the peritoneal cavity. If the newly created anastomosis shows dehiscence, the C-seal prevents leakage of feces thereby preventing anastomotic leakage. The difference of the old Coloshield compared to the C-seal is that the latter is completely biodegradable and is attached into the lumen at the anastomosis during and by means of the standard circular stapling procedure. This implies that the surgeon hardly has to alter his technique. The drain degrades over time and disappears from the colon by excretion through the anus. In 2006, the C-seal was first tested in 15 patients undergoing LAR. The C-seal pilot study showed no anastomotic leakage. In 2010 the C-seal was tested in a multicenter phase II study. Thirty-seven patients were treated with the C-seal and followed until 3 months post surgery. No serious adverse events related to the C-seal use occurred. In 2 patients the C-seal was incorrectly placed and could therefore not function properly. Both patients recovered well without complications. One patient developed anastomotic leakage leading to re-intervention within 30 days after the primary surgery. Four patients had an abscess which spontaneously drained via the rectum without a re-intervention. Two adverse events occurred during C-seal application: The C-seal was stapled double at the anastomotic site and it was not possible to extract the C-seal through the anus. The C-seal was cut loose and the remaining part of the C-seal was left in situ. The C-seal did not exert its function in these patients. Both patients recovered well without complications.
To answer the question whether the C-seal is indeed helpful in preventing anastomotic leakage necessitating re-intervention the current prospective randomized controlled study will be performed.

Multicenter randomized open phase III parallel group study.

Patient will be randomly allocated to either:

1. Standard surgery;

2. Standard surgery plus placement of C-seal.

Stratification acc. to centre, height of anastomosis and planned ostomy Y/N.

Follow-up until 1 year after surgery.

616 patients to be included.

Interim-analysis after 50 en 75% inclusion.

Study objective

The incidence of anastomotic leakage will decrease significantly with the use of the C-Seal

drain in comparison with the control group (no C-Seal drain).

Study design

Up to 30 days post surgery.

Final evaluation after 1 year.

Intervention

Use of the C-Seal drain.

The C-seal is a biodegradable thin-walled drain. It is compatible with the circular stapler used in almost all low anterior resections. It is developed to prevent extravasation of intracolonic content to the peritoneal cavity. If the newly created anastomosis shows dehiscence, the C-seal prevents leakage of faeces thereby preventing anastomotic leakage. The C-seal is completely biodegradable and is attached into the lumen at the anastomosis during and by means of the standard circular stapling procedure. This implies that the surgeon hardly has to alter his technique. The drain degrades over time and disappears from the colon by excretion through the anus.

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Eligibility criteria

Inclusion criteria

1. Any colorectal disease requiring a colorectal anastomosis to be made by a circular stapler/cutter;

2. Elective surgery;

3. Age > 18 years;

4. American Society of Anesthesiologists (ASA) classification 1, 2 or 3;

5. No clinical signs of peritonitis;

6. No major surgical or interventional procedures within 30 days prior to this study or planned surgical or interventional procedures within 30 days of entry into this study;

7. Absence of any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule; those conditions should be discussed with the patient before registration in the trial;

8. Written informed consent must be signed according to ICH/GCP and Dutch law, before patient registration and randomization;

9. Patients can only be randomized in this trial once.

Exclusion criteria

No specific exclusion criteria other than the opposite of the inclusion criteria.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-10-2011
Enrollment:	618
Type:	Anticipated

Ethics review

Positive opinion

Date:	26-09-2011
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 39412
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2933
NTR-old	NTR3080
CCMO	NL37675.042.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON39412

Study results

Summary results
N/A