Colorectal anastomosis protected by a biodegradable drain fixed to the anastomosis by a circular stapler. A Multi-Center Randomized Controlled Trial (C-seal study)

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Primary objective: efficacy of the C-seal in reducing anastomotic leakage (AL).Secondary objectives: The number of dismantled anastomoses; AL within 30 days according to the ISGRC classification; interval between the operation and AL; The pain score...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON39412

Source
ToetsingOnline

Brief title
C-seal

Condition

- Gastrointestinal therapeutic procedures

Synonym
anastomotic leakage

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: UMC Groningen

Intervention

Keyword: anastomotic leakage, C-seal, low anterior resection, rectum

Outcome measures

Primary outcome

Anastomotic leakage, necessitating an invasive intervention, in the 1st 30 days post-surgery.

Secondary outcome

Number of dismantled anastomoses; AL within 30 days according to the ISGRC classification; interval between the operation and AL; The pain score at postoperative day 3; number of ostomies (also after 1 year); late AL (diagnosed >=30 days and <1 year); total duration of hospital stay for adverse events and/or stoma closure; Interval between C-seal application and C-seal loss.

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.

Study objective

Primary objective: efficacy of the C-seal in reducing anastomotic leakage (AL).
Secondary objectives: The number of dismantled anastomoses; AL within 30 days according to the ISGRC classification; interval between the operation and AL; The pain score at postoperative day 3; number of ostomies (also after 1 year); late AL (diagnosed >=30 days and <1 year); total duration of hospital stay for adverse events and/or stoma closure; Interval between C-seal application and C-seal loss.

Study design

Multicenter randomized open phase III parallel group study.
Patient will be randomly allocated to either:
• Standard surgery.
• 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.

Intervention

Standard surgery with or without placement of C-seal.

Study burden and risks

Risk: adverse events/complications of placement of C-seal.
Burden:
No extra visits.
Presence of C-seal until loss (normally <30 days).
Monitoring loss of C-seal.
VAS pain op 3rd postoperative day.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Any colorectal disease requiring a colorectal anastomosis to be made by a circular stapler/cutter;
• Elective surgery;
• Age > 18 years;
• American Society of Anesthesiologists (ASA) classification 1, 2 or 3;
• No clinical signs of peritonitis;
• 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.

Exclusion criteria

• Incapacitated patients.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-12-2011
Enrollment:	350
Type:	Actual

Ethics review

Approved WMO Date:	29-09-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	10-11-2011
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	07-09-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	04-03-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 27437
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
Other	clinicaltrials.gov, registratienummer n.n.b.
CCMO	NL37675.042.11
OMON	NL-OMON27437