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

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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).

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27437

Bron
Nationaal Trial Register

Verkorte titel
C-Seal

Aandoening

Colorectal Surgery Anastomotic Leakage C-Seal Drain

Ondersteuning

Primaire sponsor: UMC Groningen, Dept. of Surgery
Overige ondersteuning: UMC Groningen

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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).

Onderzoeksopzet

Up to 30 days post surgery.

Final evaluation after 1 year.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	15-10-2011
Aantal proefpersonen:	618
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	26-09-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 39412
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A