The C-seal study.

No registrations found.

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

Summary

ID

NL-OMON28405

Source
NTR

Health condition

Low anterior resection, anastomotic leakage, anastomotic dehiscence, rectal cancer, surgery
In Dutch: naadlekkage, rectumcarcinoom, laag anterior resectie, chirurgie

Sponsors and support

Primary sponsor: University Medical Center Groningen, The Netherlands
Source(s) of monetary or material Support: UMCG and Polyganics B.V.

Intervention

Outcome measures

Primary outcome

To estimate the occurrence of anastomotic leakage when the C-seal is used.

Secondary outcome

1. The assessment of technical feasibility defined as technical success, determined by a gastrografin enema X-ray of the rectum one week after the operation;

2. The successful clearance of the C-seal at 6 weeks without the occurrence of a serious adverse event;

3. Estimation of patient friendliness of the drain, at one week and 6 weeks;

4. Technical success: The Technical success is defined as the successful application of the C-seal;

5. Acute procedural success: Acute procedural success is defined as the successful application of the C-seal without the occurrence of a Serious Adverse Effects (SAE) caused by the drain/protector during or directly after the procedure;

6. Procedural success: The successful placement of the C-seal and the successful clearance of the C-seal with absence of any serious adverse events up to 30 days.

Study description

Background summary

Colorectal anastomotic leakage (AL) is a serious complication in colorectal surgery leading to high morbidity and mortality rates. A new device is developed in our institute aimed at protecting the colorectal anastomosis and lowering the incidence of AL. This so called C-seal is a biofragmentable drain, which is stapled to the anastomosis with a circular stapler. It covers the luminal side of the colorectal anastomosis. The C-seal does not prevent the formation of dehiscences. However, it prevents extravasation of faeces into the peritoneal cavity. This means that a gap at the anastomotic site does not lead to leakage.

A pilot study, testing the C-seal in 15 patients, showed that the C-seal can be succesfully applied in colorectal surgery. The C-seal was well compatible with the circular stapler and easy to employ. No anastomotic leakages were observed in these 15 patients.

Study objective

In this phase II study the main objective is the assessment of the occurrence of anastomotic leakage with the use of the C-seal. The assessment will take place one week after the operation, and 6 and 12 weeks after the procedure.

Study design

1. During hospitalisation, 6 weeks and 3 months after surgery: Assessment of end points;

2. One week after surgery: Rectal contrast enema.

Intervention

Placement of the C-seal in a stapled colorectal anastomosis. C-seal is a biofragmentable drain, which is stapled to the anastomosis with a circular stapler. It covers the luminal side of

the colorectal anastomosis. The C-seal does not prevent the formation of dehiscences. However, it prevents extravasation of faeces into the peritoneal cavity. This means that a gap at the anastomotic site does not lead to leakage.

Contacts

Public
Hanzeplein 1
A.N. Morks
p/a Secr. Abdominale Chirurgie; BA 11
Groningen 9700 RB
The Netherlands
+31 (0)50 3611294
Scientific
Hanzeplein 1
A.N. Morks
p/a Secr. Abdominale Chirurgie; BA 11
Groningen 9700 RB
The Netherlands
+31 (0)50 3611294

Eligibility criteria

Inclusion criteria

1. Age > 18 years;

2. The patient requires an anastomosis, maximally 15 cm proximal from the anus;

3. The patient will receive a colorectal anastomosis by means of stapling;

4. The patient is willing and able to comply with the specified follow-up evaluation;

5. The patient must provide written informed consent prior to the procedure.

Exclusion criteria

1. Patient treatment is acute (not elective);

2. Patient is associated with infections at the time of intervention (peritonitis);

3. 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;

4. Patients with ASA classification > 3.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-02-2010
Enrollment:	35
Type:	Anticipated

Ethics review

Positive opinion

Date:	19-04-2010
Application type:	First submission

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	NL2178
NTR-old	NTR2302
Other	METc UMCG : 2009.078
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
Protection of stapled colorectal anastomoses with a biodegradable device: the C-seal feasibility study
Kolkert JL, Havenga K, ten Cate Hoedemaker HO, Zuidema J, Ploeg RJ. Accepted for publication in American Journal of Surgery.