The C-Seal study: Colorectal anastomosis protected by a biodegradable drain fixed to the anastomosis by a circular stapler: a phase II study.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Interventional

Summary

ID

NL-OMON33015

Source
ToetsingOnline

Brief title
The C-Seal study

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal neoplasms malignant and unspecified
- Gastrointestinal therapeutic procedures

Synonym
rectal cancer, sigmoid cancer

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W,Polyganics BV

Intervention

Keyword: anastomotic leakage, biodegradable drain, circular stapler, colorectal anastomosis

Outcome measures

Primary outcome

The primary endpoint is recovery of the patient without clinical manifestation

of anastomotic leakage. Anastomotic leakage is considered to be clinical

manifest if any of the following occurs:

* Relaparotomy with dismantling of the anastomosis and creation of an end

colostomy

* Relaparotomy with placement of drains in the pelvis

* Relaparotomy with creation of a diverting ostomy

* Radiologically guided drainage of any fluid in the pelvis

Secondary outcome

- The assessment of technical feasibility defined as technical succes,

determined by a gastrografin enema X-ray of the rectum (through the C-seal

drain) one week after the operation

- The successful clearance of the C-seal at 6 weeks without the occurrence of a

serious adverse event.

- Technical success: The Technical success is defined as the peroperatively

successful application of the C-seal.

- 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.

- Procedural success: The successful placement of the C-seal and the successful

clearance at 6 weeks with absence of any serious adverse events up to 30 days.

- Concentrations of MMP's, TIMP's, pro-inflammatory en pro-coagulatory factors

in blood and tissue samples will be measured. We will determine the relation

between their concentrations and the occurence of anastomotic leakage.

Study description

Background summary

Anastomotic leakge remains an serious and frequent complication after low anterior resection. The incidence of anatomotic leakage is reported variably in the literature, but is likely to be between 10 and 15 percent, depending on the indication.
Anastomotic leakage is associated with mortality and morbidity. Patient usually experience an episode of peritonitis and sepsis. Usually they end up with a definitive stoma.
The C-seal is a biodegradable drain that is stapled to the anastomosis during the operation. The drain is pulled through the anus by the circular stapler. In this way the anastomosis is sealed from the inside. Any small defects in the anastomosis will not cause leakage and are allowed to heal secundary.

In a previous phase our group performed a pilot study to the application of the C-seal. Apart from some technical difficulties related to gluing the C-seal to the cap of the stapler, this pilot study was successful. No anastomotic leakage occured in the 15 included patients.

Study objective

The primary objective of this second phase study is to estimate the occurrence of anastomotic leakage when the C-seal is used.

Secondary objectives are:
* Feasibility of applying the C-seal, especially considering the improved attachement to the circular stapler using adhesive tape
* Estimation of patient friendliness of the drain, at 14 days and 6 weeks.
* Inventarisation of complications.
* Identification of risk factors predicting the occurence of anastomotic leakage by analysing blood and tissue samples.

Study design

Multicenter study, coordinated by the UMCG. Phase II study.

Intervention

Resection of the rectum or sigmoid colon. Anastomosis by use of a circular stapler. The anvil of the stapler is placed inside the C-seal. In this wat the C-seal is stapled to the anastomosis.

If a patient is also willing to donate blood- and tissue samples for additional secondary research, 3 extra blood samples will be drawn and a small sample of the resected tissue will be used for this research.

Study burden and risks

After the operation the C-seal is pulled through the anus. Stool can pass through the C-seal and may lead to some hygienic concerns.
After 1 week a gastrografin enema X-ray study is proposed. This study is performed outside the regular routine of postoperative care.
It is conceivable that for some reason the C-seal gets clogged. This may lead to anastomotic leakage, peritonitis, sepsis and death. We estimate this risk as very small.

No additional interventions are necessary for the collection of blood and tissue samples. Blood will be drawn at a moment it is drawn anyway for preparation of the surgical intervention and during the surgical intervention, blood will be drawn via a peripheral venous.

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

Age > 18 years;
The patient requires an anastomosis, maximally 15 cm proximal from the anus
The patient will receive a colorectal anastomosis by means of stapling;
The patient is willing and able to comply with the specified follow-up evaluation;
The patient must provide written informed consent prior to the procedure.

Exclusion criteria

Patient treatment is acute (not elective);
Patient is associated with infections at the time of intervention (peritonitis);
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;
Patients with ASA classification >3;

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-02-2010
Enrollment:	35
Type:	Actual

Medical products/devices used

Generic name:	C-Seal
Registration:	No

Ethics review

Approved WMO

Application type:	First submission
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

No registrations found.

In other registers

Register	ID
CCMO	NL27454.042.09