Protection of colorectal anastomoses with a biodegradable device: The C-SEAL feasibility study.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25108

Source
NTR

Brief title
N/A

Health condition

COLORECTAL CANCER
ANASTOMOTIC LAEKAGE

Sponsors and support

Primary sponsor: UNIVERSITAIR MEDISCH CENTRUM GRONINGEN; POLYGANICS BV
Source(s) of monetary or material Support: SENTER-NOVEM

Intervention

Outcome measures

Primary outcome

Position of sheath after one week, demonstrated by water-soluble contrast enema imaging.

Secondary outcome

- Userfriendliness

- Compatibility with stapler device

- Patient confort

- Duration of degradation

- Anastomotic leakage

Study description

Background summary

Colorectal surgery is associated with a high morbidity and mortality due to anastomotic leakage. We have assessed the feasibility of a new biodegradable intraluminal sheath, designed to avoid anastomotic leakage. It was tested in fifteen patients. The sheath was well compatible to the standard stapler device used in colorectal surgery and easy to employ. Patients experienced only minimal discomfort due to the sheath. No radiological or clinical leakage was observed.

Study objective

Protection with a biodegradable sheath will reduce the number of anastomotic leakage.

Study design

- One week postoperative

- 6 weeks postoperative

- 3 months postoperative

Intervention

Prior to performing a colorectal anastomosis, a biodegradable sheath was glued to the anvil of the circular stapler. in doing so, firing the circular stapler resulted in a fixation of the protective drain to the tissue just proximally of the simultaneously made anastomosis.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age 18-80.

2. Patient requires anastomosis, maximally 15 cm from the anus.

3. Patient will recieve a colorectal anatomosis by means of stapling.

4. Patient is willing and able to comply with the specified follow-ip evaluation.

5. Patient or legally representative has given written consent.

Exclusion criteria

See inclusion, if not, than exclusion

Study design

Design

Study type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2005
Enrollment:	15
Type:	Actual

Ethics review

Positive opinion

Date:	06-06-2008
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	NL1293
NTR-old	NTR1340
Other	MEC University Medical Center Groningen : Senter grant NR TSGE 3141
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A