Adaptive anastomosis for anterior resection in sigmoid and proximal rectal cancer or premalignant lesions: a multicentre non-randomised clinical effectiveness trial (ADAPT)

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Ethical review	Approved WMO
Status	Pending
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Observational invasive

Summary

ID

NL-OMON57394

Source
ToetsingOnline

Brief title
ADAPT trial

Condition

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

Synonym
bowel cancer, Colorectal cancer

Research involving

Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Carpo Novum AB

Intervention

Keyword: Adaptive anastomosis, Anastomotic Leak, Anterior resection, Colorectal Cancer

Outcome measures

Primary outcome

The primary endpoint is the anastomotic leak rate within 30 days after surgery

Secondary outcome

Secondary outcome measures are: anastomotic leak rate at 90 days and 1 year postoperatively, intra- and postoperative complications, readmissions, the intra-operative effectiveness and efficiency of the C-REX device, surgeon satisfaction with the C-REX RectoAid Cath, time to evacuation of the anastomotic ring, quality of life, cost-effectiveness, and stoma-free survival.

Study description

Background summary

Anastomotic leakage (AL) after colorectal surgery remains a significant challenge in current day to day practice. Anastomotic leaks are associated with increased morbidity and mortality, poorer oncological outcomes, a reduction in quality of life and poses a significant socio-economic financial burden.

Despite advances in surgical procedures and improvements to surgical stapling devices, AL rates for colorectal procedures still range from 3% up to 25%, with higher rates for more distal anastomosis. Multiple risk factors such as male gender, diabetes, smoking, low preoperative haemoglobin levels, epidural analgesia, neo-adjuvant radiotherapy and technical aspects related to the formation of the anastomosis have been identified.

The routine method for construction of the anastomosis after an anterior resection (AR) is a cross stapled circular anastomosis. The inflammatory immune response in combination with a collagenase activating foreign body reaction to the staplers delays gastrointestinal wound healing and increases the risk of AL. Furthermore, the crossing of staples lines is a known risk factor for AL, particularly for a circular and linear stapler line that create *dog ears*.

An adaptive anastomotic technique using a compression device eliminates foreign body material in the anastomosis reducing the negative effects on wound healing and could therefore potentially lower the incidence of AL. The compression anastomotic device also avoids cross stapling and the formation of *dog ears*. A novel adaptive compression anastomosis device, the C-REX RectoAid Cath has been shown to be feasible and safe for anastomosis after colorectal resections in small single institution cohorts. A multicentre trial is needed to assess the true efficacy of the C-REX RectoAid Cath in a larger cohort of patients undergoing AR for colorectal cancer or premalignant lesions.

Study objective

The aim of this trial is to investigate the safety and efficacy of an adaptive anastomosis using the C-REX RectoAid Cath following elective anterior resection for sigmoid or proximal rectal cancer, or premalignant lesions not amenable tot endoscopic resection.

Study design

The ADAPT trial is a prospective, non-randomised, multicentre clinical effectiveness trial.

Study burden and risks

Patients will receive standard post-operative follow-up according to local protocol after elective AR. Additionally, patients are asked to fill in questionnaires pre-operative, 90 days and 1 year after the operation to assess functional outcomes/quality of life and to perform a health economic analysis. Some of these questionnaires are already standard practice for many of the participating sites. Furthermore, the use of the adaptive anastomosis technique, requiring the patient to expell the anastomotic ring with the feces and participation in medical research can be experienced as a burden by the participant.

Different to standard AR with cross stapling anastomosis will be that patients need to expel the anastomotic ring after approximately 10 days. When the anastomotic ring is not be expelled within 14 days after surgery, the ring will be removed manually. According to the guideline synopsis of non-metastatic colorectal cancer, a routine CT-scan and endoscopy at one year will be

performed for follow-up and will allow for assessment of long-term anastomotic integrity and patency.

The expected benefit to patients will be a lower anastomotic leak rate compared to the standard treatment.

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

1. Male or female age >= 18 years old.
2. Biopsy proven cancer of the sigmoid colon or proximal rectum (cT1-4aN0-2M0) that require AR as the procedure of choice.
3. premalignant lesions not amenable to endoscopic resection, that require AR as the procedure of choice.

4. Suitable for curative AR
5. Suitable for elective laparoscopic or robotic surgery
6. Cognitive ability to take part in the study, to understand the information the patient receives about participating in the study, to provide informed consent and to agree to complete the questionnaires.

Exclusion criteria

1. Pre-existing health conditions requiring emergency surgery, such as intestinal obstruction or perforation, local or systemic infections, peritonitis, or intestinal ischemia.
2. Cancer with distant metastases (TNM Stage IV).
3. Intestinal or anal stenosis or other obstructions distal to the planned anastomosis.
4. Prior pelvic radiation including neoadjuvant chemoradiotherapy.
5. Contraindications to general anaesthesia.
6. Need for defunctioning ileostomy (intention to treat).
7. Patients who have a contra-indication for or are unable to receive preoperative bowel preparation or at least two enemas prior to surgery.
8. Immunocompromised patients e.g. taking steroids or receiving immunotherapy.
9. Any condition that, in the opinion of the investigator, may interfere with the study conduction. In particular, any condition which can cause significant alteration of colonic wall thickness such as chronic and repeated infection (e.g. diverticulitis) which may impair the use of C-REX RectoAid Cath

Study design

Design

Study phase:	2
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2025

Enrollment:	120
Type:	Anticipated

Medical products/devices used

Generic name:	C-REX RectoAid Cath
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	14-03-2025
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL88846.018.25