Predictive factors for anastomotic leakage after colorectal surgery (pREdictVE factors for AL --> REVEAL)

Published: 10-06-2015
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To investigate whether recently identified patient-specific factors can predict the occurrence of anastomotic leakage in patients undergoing elective surgery for colorectal cancer.
Secondary: to develop a predictive model/diagnostic algorithm for...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON50527

Source
ToetsingOnline

Brief title
REVEAL

Condition

- Gastrointestinal neoplasms malignant and unspecified
- Gastrointestinal therapeutic procedures

Synonym
A leak where the intestine was connected back together., Anastomotic leakage

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Academisch fonds van het MUMC+

Intervention

Keyword: anastomotic leakage, colorectal cancer, markers

Outcome measures

Primary outcome

The primary outcome parameter in this study is the occurrence of anastomotic leakage. Anastomotic leakage is defined:

1) Leakage of bowel content and/or gas from the surgical connection between the 2 bowel ends into the abdomen or pelvis with either spillage and/or fluid collection around the anastomotic site or extravasation through a wound, drain site of anus;

2) Clinical manifestion causing fever, abcess, septicaemia, peritonitis and/or organ failure; and

3) Confirmation by imaging technique (e.g. radiograph, endoscopy, CT-scan, MRI, sonography) or by digital rectal examination or anoscopy and/or proctoscopy for low rectal anastomoses.

Secondary outcome

Secondary study parameters/endpoints:

• Intestinal microbiome in fecal sample

• I-FABP,SM22, Calprotectin, CRP, Citrullin, complement factors in blood

• VOCs in exhaled air

• COX-2 & MBL polymorphisms in buccal smear

• L3-index measurements & evaluation of atherosclerosis on CT-scans

• SNAQ & MUST scores

Study description

Background summary

Colorectal cancer is the fourth most common cause of cancer death worldwide, estimated to be responsible for almost 610,000 deaths in 2008. Surgery remains the predominant curative treatment type for colorectal cancer, but has a major impact on the patient*s wellbeing by demanding large amounts of metabolic reserves. This can lead to the development of frequently observed and severe postoperative complications. The most important complication after colorectal surgery is anastomotic leakage (AL), which has an incidence of 8-15% in the Netherlands. AL is associated with high short-term mortality rates of up to 40%. Even though many attempts have been made to reduce the incidence of this dreaded complication, none of these interventions have been successful so far. Despite proper patient selection and improvement in surgical techniques, the percentage of AL has been stable for years.

Study objective

To investigate whether recently identified patient-specific factors can predict the occurrence of anastomotic leakage in patients undergoing elective surgery for colorectal cancer.
Secondary: to develop a predictive model/diagnostic algorithm for anastomotic leakage based on the study findings.

Study design

This study will be a multicentre prospective observational study that will be conducted at Maastricht University Medical Centre (MUMC, Maastricht, Netherlands), Zuyderland Medical Centre (Sittard and Heerlen, Netherlands) and VieCuri Medical Centre (Venlo, Netherlands).

Study burden and risks

There are hardly any risks involved in participating in this study. Plasma samples will be obtained in clinical setting, regularly together with plasma sampling for laboratory measurements. This is a normal venepuncture and the only risk is a small local hematoma. In addition to plasma sampling, we will obtain buccal swabs samples, faeces and exhaled air. Taking a buccal swab is a way to collect DNA from the cells on the inside of a person's cheek; this is a relatively non-invasive way to collect DNA samples for testing. Stool samples will be collected in the hospital in order to store them within 4 hours at -80°C for further analysis. Patients can collect their own stool in a clean, dry screw-top container, if necessary with the assistance of a nurse. Exhaled air will be obtained by asking patients to breathe into a 3L Tedlar bag. This

takes approximately 5 minutes and patients will have to breathe at normal frequency and with normal volume, therefore it will not cause physical strain. Time investment is minimal since testing and data collection will be planned during the hospital stay. No additional hospital visits are required. Both Short Nutritional Assessment Questionnaire (SNAQ) en Malnutrition Universal Screening Tool (MUST) will be filled out by nurses in the clinical setting.
This is part of standard care of colorectal patients at time of registration.
In retrospective, questionnaires of patients with anastomotic leakage will be analysed to compare them with those of patients without anastomotic leakage.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Inclusion criteria

-18 years or older
- In need of laparoscopic or open large bowel resection with anastomosis as standard treatment for colorectal carcinoma or large adenomas (tubular,

tubulovillous, villous and sessile serrated adenomas)

Exclusion criteria

- patients with colorectal cancer or a premalignant condition not receiving an anastomosis
- patients who underwent abdominal surgery in the past four weeks
- pregnant patients
- cognitively impaired patients

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-09-2015
Enrollment:	588
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	10-06-2015
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO Date:	26-10-2015
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	28-12-2016
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	03-05-2017
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
Other	METC142073
CCMO	NL48370.068.14

Study results

Date completed:	01-07-2021

Actual enrolment: 574

Summary results
Trial ended prematurely