Analysis of Predictive Parameters of Evident Anastomotic Leakage II

Published: 24-11-2015
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ObjectiveTo identify biomarkers for CAL in drain fluid and serum, in addition to RT-PCR for E. faecalis, that increase specificity and positive predictive value.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal inflammatory conditions
Study type	Observational invasive

Summary

ID

NL-OMON44055

Source
ToetsingOnline

Brief title
APPEAL-II study

Condition

- Gastrointestinal inflammatory conditions
- Gastrointestinal therapeutic procedures

Synonym
Anastomotic Insufficiency, Anastomotic Leakage, Leakage of Intestinal Suture

Research involving
Human

Sponsors and support

Primary sponsor: UZ Leuven
Source(s) of monetary or material Support: Medtronic

Intervention

Keyword: Anastomotic Leakage, Colorectal surgery, Drain fluid, Early detection

Outcome measures

Primary outcome

The primary outcome measure of the APPEAL-study is anastomotic leakage, defined as an insufficiency of the anastomosis, demonstrated by either endoscopy, radiologic studies or operation and leading to a clinical state that requires an intervention.

Secondary outcome

Not applicable

Study description

Background summary

The most important and frustating complication of colorectal surgery is colorectal anastomotic leakage (CAL). The incidence of CAL varies from 3% and 19% and mortality rate due to CAL vary between 10% and 20%. To date, CAL is suspected when certain signs and symptoms are present and confirmation occurs by imaging and/or reoperation. CAL is generally confirmed six days to two weeks after the operation at which point the patient is very ill. In order to reduce the mortality and morbidity rates, it is necessary to confirm the diagnosis of CAL before clinical signs and symptoms occur.

Study objective

Objective
To identify biomarkers for CAL in drain fluid and serum, in addition to RT-PCR for E. faecalis, that increase specificity and positive predictive value.

Study design

To achieve the objective all included patients receive a drain that will be removed at the third postoperative day. During this period drain fluid will be retrieved daily and a blood examination, including CRP, will be performed as

well.
Drain fluid is collected daily, on postoperative day one to three, centrifuged and stored at * 80 °C. Analysis will be performed in batch and, based upon literature, consist of following groups of parameters:
* Bacteria: E. faecalis
* Immune-modulating parameters: IL-1, IL-6, IL-10 and TNF-*
* Pancreas enzymes: Amylase
* Tissue repair modulating parameters: MMP * 2 en MMP - 9
* Inflammatory parameters: LBP
* Metabolic parameters: Lactate, glucose, pH
Blood samples will be analysed for CRP.

Study burden and risks

Participation in this study provides no benefits to the patient. The load in the context of the study will consist of invasive procedures to obtain additional body material. The hospitalisation of the patients in this study will not be prolonged. A drain is placed during operation which will remain in place for 3 days. Normally, the operator decides during the operation if it is necessary to place a drain. However, there are no clear guidelines for this decision. A drain is placed more frequently in open surgery compared to laparoscopic surgery. A drain could prevent complications after surgery. However, there are also disadvantages to a drain.

- The drain may cause pain at the level of the skin

- While walking you should take the drain.

In addition, blood samples are taken at the three postoperative days. In general there is no blood taken at the second postoperative day. The collection of blood does have some risks for some patients. There is a risk of developing a hematoma and it is possible to have a bleeding. However, the occurence of a bleeding is stronly related to coagulation disorders.

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

- Informed consent
- Primary anastomosis
- All patients with a postoperative drain at the anastomotic site after one of the following procedures:
* Total Mesorectal Excision (TME)
* Partial Mesorectal Excision (PME)
* Anterior resection with construction of a colorectal or colo-anal anastomosis

Exclusion criteria

- Pregnancy
- Age < 18 years
- No informed consent
- No drain
- Emergency surgery

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-01-2016
Enrollment:	225
Type:	Actual

Ethics review

Approved WMO Date:	24-11-2015
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	09-12-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL52251.078.15