APPEAL-study
Analysis of Predictive Parameters for Evident Anastomotic Leakage
A Multicenter Cohort Study

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29099

Source
Nationaal Trial Register

Brief title
APPEAL-study

Health condition

Anastomotic leakage, colorectal surgery, drainage fluid, biomarkers
Naadlekkage, colorectale chirurgie, drainvocht

Sponsors and support

Primary sponsor: Erasmus MC, Rotterdam, The Netherlands
Source(s) of monetary or material Support: Technologiestichting STW (Stichting Technische Wetenschappen)

Intervention

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. These interventions are:

a) Therapeutic drainage

b) Use of therapeutic antibiotics

c) Any surgical intervention, for example:

• Construction diverting stoma

• Construction new anastomosis

• Surgical disconnection of the anastomosis

• Suturing

Secondary outcome

Comparison of the studied potential biomarkers in terms of speed, accuracy and cost-effectiveness
Study the capacity of the potential biomarkers to distinguish between clinically manifest and subclinical anastomotic leakage

Study description

Background summary

The main complication after colorectal surgery is anastomotic leakage (AL), with an incidence varying between 5% and 15%. In an insufficient anastomosis, wall defects can develop through which non-sterile contents of the colon can leak into the abdominal or pelvic cavity. This can cause severe infections that can lead to sepsis, multiple organ failure and death. Mortality rates are approximately 10% to 20%.
Observation of clinical signs and symptoms of AL, the current diagnostic tools, is not very

specific. They can mimic several common, less severe, postoperative infections. Diagnostic tests for these infections can delay the actual diagnosis. On top of that, when AL has already progressed to a state of clinical manifestation, the patient is already ill and treatment should be initiated. Imaging modalities, more specific abdominal CT-scans and contrast enemas, are normally used to confirm a clinical diagnosis of AL (4). This means that imaging is done when the patient has already shown signs and symptoms and treatment has to be initiated. In short, it can be stated there is much need for an objective biomarker of AL.

An accepted method for prevention of complications of AL after colorectal surgery is prophylactic drainage. This enables postoperative evacuation of blood and wound fluid collections and therefore decreases the risk of infection. The aim of the APPEAL-study is to analyse these collections, retrieved from the drain's reservoir, for potential biomarkers of AL in an early stage. Drainage fluid will be collected during 5 days. The fluid will be processed in the laboratory of microbiology, where a culture is done and the remaining fluid is centrifugated and frozen for later, in batch, analysis. The clinical chemical tests will be done in batch in the Erasmus MC. The cultures, centrifugation and freezing of the fluids will be done at the laboratory of microbiology of the participating medical center.
The results of the cultures and clinical chemical analyses will be known for the researcher, not for the patient and not for the medical doctors treating the patient. The results of the group with anastomotic leakage will be compared with the results of the group without anastomotic leakage in order to define one or more biomarkers.

Study objective

Drainage fluid of patients that received a primary colorectal anastomosis contains one or more biomarkers for anastomotic leakage that allow diagnosis of this complication in an early postoperative phase. The aim of this study is to identify these potential biomarkers.

Study design

Drainage fluid will be taken from the drain during the first 5 postoperative days.

During the first postoperative consultation after approximately one month the patient will be evaluated for signs of anastomotic leakage.

Analysis of drainage fluid will be done when a sufficient number of samples is collected for efficient analysis.

Intervention

Prophylactic drainage after colorectal surgery is common practice. When a drain is left behind during operation the patient can be included in the study. The only difference with routine practice is that the drain will stay in place until the fifth postoperative day, which is longer than in routine practice. When complications or discomfort occurs before this term the drain will be removed.

Contacts

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Eligibility criteria

Inclusion criteria

1. All patients in which a drain has been placed at the anastomotic site after one of the following procedures:

- Left hemicolectomy

- Sigmoid resection

- Anterior resection (high & low)

- Total Mesorectal Excision

- Subtotal colectomy with ileo-rectal or ileo-anal anastomosis

2. Informed consent

3. Primary anastomosis

Exclusion criteria

1. Pregnancy

2. Age < 18 years

3. Refusing to participate

4. Urgent operation

5. No drain

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-02-2007
Enrollment:	273
Type:	Anticipated

Ethics review

Positive opinion

Date:	27-03-2008
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	NL1213
NTR-old	NTR1258
Other	MEC : 2006-183
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A