The APPEAL-study
Analysis of Parameters Predictive for Evident Anastomotic Leakage

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Primary objectiveTo define a parameter, or parameters, in peritoneal drain fluid that have diagnostic value for clinically manifest anastomotic leakage of a colorectal anastomosis in the early postoperative period.Secondary objectivesTo compare the...

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

Summary

ID

NL-OMON29884

Source
ToetsingOnline

Brief title
The APPEAL-study

Condition

- Gastrointestinal inflammatory conditions
- Gastrointestinal therapeutic procedures

Synonym
anastomotic insufficiency, leakage of intestinal suture

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Stichting Technische Wetenschappen

Intervention

Keyword: Anastomotic leakage, Early diagnostics

Outcome measures

Primary outcome

Primary outcome measure

The primary outcome measure of the APPEAL-study is anastomotic leakage, defined as an insufficiency of the anastomosis, demonstrated by either endoscopy, radiological examination or operation, 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:

* Surgical disconnection of the anastomosis

* Construction diverting stoma

* Suturing

* Construction new anastomosis

Secondary outcome

To compare the evaluated parameters for their accuracy, cost-effectiveness and speed.

To investigate if, with these parameters, a distinction can be made between sub-clinical and clinical anastomotic leakage.

Study description

Background summary

The main complication after colorectal surgery is anastomotic leakage, 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 cavity. This can cause peritonitis that leads to sepsis, multiple organ failure and, finally, death in approximately 10 % to 20 %. Current diagnostic methods include observation of clinical symptoms and imaging, both with several disadvantages. Observation of clinical symptoms is not specific; the symptoms can mimic several common, less severe, postoperative infections, which delays the actual diagnosis. On top of that, when anastomotic leakage has already progressed to a state of clinical manifestation, the patient is already ill and treatment should be initiated. Imaging is used to confirm a clinical diagnosis of anastomotic leakage. This means that when imaging is done the patient is already ill and treatment should be initiated. An accepted method for prevention of this complication is prophylactic drainage. This enables postoperative evacuation of blood and wound fluid collections that could lead to infection. In this study these collections, retrieved from the drain*s reservoir, will be analysed for parameters with potentially diagnostic value for anastomotic leakage.

Study objective

Primary objective
To define a parameter, or parameters, in peritoneal drain fluid that have diagnostic value for clinically manifest anastomotic leakage of a colorectal anastomosis in the early postoperative period.

Secondary objectives
To compare the evaluated parameters for their accuracy, cost-effectiveness and speed.
To investigate if, with these parameters, a distinction can be made between sub-clinical and clinical anastomotic leakage

Study design

The APPEAL-study will be a multicentre cohort study.
The participating hospitals will be asked to include 30 patients every year. This is possible since each centre will operate approximately 50 to 80 patients a year suitable for the APPEAL-study.
For now 8 centres have agreed to participate and two more will be asked to do so as well, so that the total number of centres will come to ten. This results in 300 patients in approximately a year.
The patients who undergo a colorectal operation, mentioned in the inclusion criteria, will be included at the moment of hospitalisation by a physician. They will receive an explanation of the contents of the APPEAL-study, a patient

brochure and they will be asked to give their informed consent. If the patient decides to participate a drain will be left in the abdomen during the operation and will remain in place for five days. After the procedure, each postoperative day, the overnight drain fluid collection will be send to the laboratory of clinical chemistry and microbiology for further processing (table 1). With each 20 included patients (100 samples) analysis of the parameters mentioned in table 1 will be done.

Study burden and risks

The patients will receive a drain which remains in place during 5 days unless the treating physician decides otherwise. The burden and risk that go along with placement of the drain are minimal.
Withdrawl of drainfluids from the reservoir will take place each day and is considered not to be a burden.

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

All patients who have received a drain after the following procedures:
- left hemicolectomy
- sigmoid resection
- high anterior resection
- low anterior resection
- subtotal colectomy with ileo-rectal or ileo-anal anastomosis
Primary anastomosis
Informed consent

Exclusion criteria

* Pregnancy
* Age < 18 years
* Refusing to participate
* Urgent procedure
* No drain

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-01-2008
Enrollment:	270

Type:	Actual

Ethics review

Approved WMO Date:	04-09-2006
Application type:	First submission
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	NL12644.078.06