Early Detection of Anastomotic Leakage after Colon, Esophageal and Gastric Surgery

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Primary objective:To find a relation between several laboratory test, clinical parameters and riskfactors to the occurrence of anastomotic leakage after a colectomy, esophagectomy or gastrectomy.Secondary objective:To find a combination of factors...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Procedural related injuries and complications NEC
Study type	Observational invasive

Summary

ID

NL-OMON37065

Source
ToetsingOnline

Brief title
LEAK

Condition

- Procedural related injuries and complications NEC
- Gastrointestinal therapeutic procedures

Synonym
Anastomotic dehiscence, Anastomotic leakage

Research involving
Human

Sponsors and support

Primary sponsor: Atrium Medisch Centrum
Source(s) of monetary or material Support: Maatschap Heelkunde Zuid-Limburg en de

Intensive Care te Heerlen

Intervention

Keyword: Anastomotic Leakage, Colon surgery, Esophageal surgery, Gastric surgery

Outcome measures

Primary outcome

The following serum blood values will be measured and their relationship with anastomotic leakage will be analyzed between patients with anastomotic leakage and control patients without anastomotic leakage.

* Leucocyte count and differentiation

* C-reactive protein

* Procalcitonin

* Lactate

* Creatinin

The outcome of the study is the occurrence of anastomotic leakage confirmed by CT, water soluble enema, explorative surgery or pathology within 28 days after initial surgery.

Secondary outcome

In addition, the following clinical parameters and patient characteristics will be recorded and compared between patients with anastomotic leakage and control patients without anastomotic leakage.

* Age

* Gender

* American Society of Anesthesiologists (ASA) classification

* Body mass index (BMI)

* Intoxication (smoking, alcohol, drugs)

* Malnutrition universal screening tool (MUST) score

* Systemic steroid or Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) use in the last 4 weeks

* Diabetes mellitus

* Cardiac comorbidity

* Pulmonary comorbidity

* Neoadjuvant therapy

* Laparoscopy or open

* Distance of anastomosis to anal verge

* Protective stoma

* Additional procedures

* Peroperative blood loss

* Number of peroperative blood transfusions

* Duration of operation

* Severity of peritonitis as scored by operating surgeon on a 1-5 scale

* Quality of anastomosis as scored by operating surgeon on an 1-5 scale

* Need for and duration of mechanical ventilation or oxygen support

* Need for inotropic drugs.

* Patient wellness scored on a three-point scale by the physician

* Duration of hospital admission

If possible, together with the results of the laboratory tests, these

parameters will be combined into a score to early detect anastomotic leakage in

future patients.

Study description

Background summary

Anastomotic leakage is a major and not uncommon complication in gastro-intestinal surgery. The incidence ranges from 2 * 19% for colon resections, around 11 * 20% for esophagus resections and 5 * 8% for gastric resections. These account for substantial mortality and morbidity. To decrease mortality, early detection and intervention is effective. However, early detection of anastomotic leakage may be difficult since symptoms can sub-clinical until major complications develop. Most are detected five to seven days postoperatively or even later. Computer tomography (CT) as well as water soluble enema are both good diagnostics for detection of anastomotic leaks but the timing of use of these highly depends on the surgeon*s clinical suspicion. This calls for the need of early indicators of anastomotic leakage which can provide a useful tool to help surgeons detect high risk patients in an early stage and continue to additional diagnostics or surgical intervention. As of this moment, no reliable indicators have been found. Some studies have found markers that are related to anastomotic leakage such as leucocyte count, creatinin and C-reactive protein (CRP) as well as clinical parameters as fever and pulmonary symptoms. However, these lack the sensitivity and specificity for proper decision making. This study will analyse multiple standard laboratory tests and clinical parameters in relation to anastomotic leakage after colectomy, esophagectomy or gastrectomy. Each parameter/test will be analysed separately as well as in combination with other parameters/tests. In addition, there will be searched for a combination of factors that can reliably predict and/or exclude anastomotic leakage to lower the number of unnecessary operation and CTs.

Study objective

Primary objective:
To find a relation between several laboratory test, clinical parameters and riskfactors to the occurrence of anastomotic leakage after a colectomy, esophagectomy or gastrectomy.

Secondary objective:
To find a combination of factors to assess the likelihood of anastomotic

leakage in order to reduce the number of negative CT-scans and reoperations.

Study design

Prospective observational study.

Study burden and risks

The burden for included patients will be minimal since this will only include 5 venapunctures which in the majority of cases will be part of standard medical care. In addition patients will be contacted 28 days after inclusion for some short questions which will take a maximum of 10 minutes.
The following risks/complications are associated with the venapunctures:
- hematoma
- bleeding
- pain

These complications have a very small risk of causing permanent damage/complaints to the patient.

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

Patients who will undergo one of the following types of surgery will be included:
- (partial) colectomy with a primary anastomosis
- esophagectomy with gastric interposition
- (partial) gastrectomy

Exclusion criteria

Previous gastro-intestinal surgery in the last 2 months.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	308
Type:	Anticipated

Ethics review

Approved WMO

Date:	18-07-2012
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL40556.096.12