

# SmartCheck- Scoring Meets the ARt of Teamwork

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Validate the presence and correlation of intraoperative modifiable risk factors for colorectal seam leaks.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Gastrointestinal therapeutic procedures
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON49064

### Source

ToetsingOnline

### Brief title

SmartCheck

### Condition

- Gastrointestinal therapeutic procedures

### Synonym

Bowel resections, colorectal resections

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Vrije Universiteit Medisch Centrum

**Source(s) of monetary or material Support:** Ministerie van OC&W

### Intervention

**Keyword:** anastomotic leakage, colorectal surgery, modifiable risk factor, perioperative care

## Outcome measures

### Primary outcome

Main parameter is the amount of present intraoperative risk factors for CAL:

- 1 hemoglobin level,
- 2 glucose level,
- 3 subjective assessment of contamination of the operating field,
- 4 inotropic support,
- 5 timing of preoperative antibiotics,
- 6 administration of epidural,
- 7 operating time
- 8 temperature

### Secondary outcome

1. Reduction of CAL by enhanced validation
2. Confirm the association between the intraoperative risk factors with CAL

## Study description

### Background summary

Colorectal anastomotic leakage (CAL)

In colorectal surgery the only alternative for a stoma is a colorectal anastomosis by reconnecting the two ends of intestine.<sup>1</sup> The problem of this procedure is leakage of the attachment<sup>2</sup>. The consequences of an anastomotic leak are well known amongst surgeons. Symptoms such as abdominal pain, palpitations, fever and a bloated abdomen along with characteristic blood tests, are indicative for urgent surgical re-intervention<sup>3</sup>. The surgery area needs to be washed out and a fecal diversion is necessary otherwise gastrointestinal contents can cause further complications. This is associated with a prolonged stay in the intensive care unit, and a mortality rate of

approximately 10% to 15%<sup>4</sup>. In addition, a leakage has been associated with an increased local relapse and a reduced long term survival after colorectal cancer surgery<sup>5,6</sup>. The 30-day mortality as well as the readmission rate and Length Of hospital Stay (LOS) rises substantially with CAL, thereby increasing the treatment costs.

Colorectal anastomotic leakage is an important topic in scientific research due to the severe consequences. A number of anastomotic studies resulted in a decline of leakage. Nevertheless, CAL remains a surgeons most feared complication with an incidence varying from 8-13%<sup>7-10</sup>. Main research focus has been directed towards optimization of surgical techniques and determining relevant risk factors.<sup>7</sup> Previous studies have revealed that patient-related factors, such as male gender and higher American Society of Anesthesiologist (ASA) score, are associated with CAL.<sup>4,10-13</sup> Some of them have been included in a colon leakage score (CLS) to determine in advance whether an anastomosis or stoma should be constructed<sup>17,18</sup>. The downside of this score is that after determining a high CAL-risk, there is no possibility to change or improve the risk factors. There are pre-habilitation programs that improve the patient's preoperative status, focusing on the risk factors related to the patient's lifestyle<sup>19</sup>. But also, an optimal surgical environment proves to have a beneficial effect on the healing of the anastomosis<sup>22,23</sup>. For instance, anesthesiological/hemodynamic parameters were revealed to be related to the risk of insufficient anastomotic healing, perfusion and ischemia. Previous international research by our research group showed seven risk factors for CAL that can be optimized in the perioperative setting.<sup>32</sup> Their distribution amongst the study population is shown in figure 1. These are the following seven intraoperative risk factors for CAL; low preoperative hemoglobin (OR 5.21,  $p < 0.001$ ), fecal contamination of the operative field (OR 3.14,  $p < 0.001$ ), hyperglycemia (OR 3.05,  $p = 0.002$ ), duration of surgery of more than 3 hours (OR 1.83,  $p = 0.014$ ), inotropic support (OR 1.78,  $p = 0.010$ ), inadequate timing of preoperative antibiotic prophylaxis (OR 1.57,  $p = 0.047$ ) and application of epidural analgesia (OR, 1.75,  $p = 0.014$ ).<sup>32</sup> These are modifiable intraoperative factors that are able to be optimized. These parameters are not currently being explicitly monitored or optimized during the operation, or, in particular, while making the anastomosis. Additionally, optimal values or guidelines for optimization for these modifiable risk factors are not established.

While a study is currently being designed to investigate whether optimization leads to decrease in incidence of CAL. The aim of this multicenter prospective cohort study is enhanced validation of these modifiable risk factors for CAL. Repeated emphasis of the importance of intraoperative risk factors could potentially automatically lead to a reduction in abnormalities, the phenomenon known as the Hawthorne effect. By raising awareness around important risk factors this could lead to a possible reduction of CAL.

## **Study objective**

Validate the presence and correlation of intraoperative modifiable risk factors for colorectal seam leaks.

### **Study design**

A prospective multi center cohort study.

### **Study burden and risks**

There are no risks or additional burden.

## **Contacts**

### **Public**

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## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adults (18-64 years)

Elderly (65 years and older)

## Inclusion criteria

- \* Subjects undergoing colorectal surgery with any kind of anastomosis.
- \* Can speak and understand the Dutch language.
- \* Is pre-operatively in good physical health as defined by ASA (American Society of Anaesthesiologists) physical status classification system 1, 2 and 3.
- \* Is capable of giving informed consent.

## Exclusion criteria

- No exclusion criteria.

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Prevention

### Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-07-2020

Enrollment: 1100

Type: Anticipated

## Ethics review

Approved WMO

Date: 24-07-2020

Application type: First submission

Review commission: METC Amsterdam UMC

## 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	NL71966.029.19