Markers of anastomotic leakage

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The aim of this pilotstudy is to find (an) accurate marker(s) of anastomotic leakage at an early postoperative timepoint.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Observational invasive

Summary

ID

NL-OMON34191

Source
ToetsingOnline

Brief title
Markers of anastomotic leakage

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
anastomotic dehiscence, Anastomotic leakage

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Anastomotic leakage, Calprotectin, Colorectal surgery, Markers

Outcome measures

Primary outcome

Calprotectin (plasma + intestinal content)

Secondary outcome

C-reactive Protein (CRP)

Intestinal-Fatty Acid Binding Protein (iFABP)

Liver-Fatty Acid Binding Protein (LFABP)

Myeloperoxidase

Matrix metalloproteinases 8 + 9

Study description

Background summary

Anastomotic leakage is one of the most dreaded complications following colorectal surgery. Pathofysiology of anastomotic leakage is characterized by intestinal content leaking into the abdominal cavity, resulting in inflammation, sepsis, and eventually death. Diagnosis is challenging: clinical signs and symptoms are often non-specific, leakage is frequently missed on CT imaging and adequate laboratory tests are lacking. Therefore, sensitive and specific markers are needed to detect anastomotic leakage early after colorectal surgery. An accurate marker can improve clinical management. Laparotomy or drainage of intraabdominale abcesses can be performed at an earlier timepoint and needless surgery can be prevented, reducing morbidity and mortality.

Study objective

The aim of this pilotstudy is to find (an) accurate marker(s) of anastomotic leakage at an early postoperative timepoint.

Study design

1) The highest incidence of anastomotic leakage is reported between postoperative day 3 and 7. Therefore, venous blood is collected daily (2-3 ml

at a time), starting at day 0 (on which surgery is performed) until postoperative day 7.
2) In patients with ostomy and great risk of anastomotic leakage (tumor < 6 cm from the anorectal verge, history of smoking, alcohol abuse, preoperative radio/chemotherapy), a cotton roll (diameter 1.5 cm) is inserted in the rectum daily, starting at postoperative day 1 until postoperative day 7. The cotton roll is inserted by a nurse in the morning and is removed at the end of the day (about 8 hours in situ).
3) In patients in which ostomy is not performed, faeces is collected daily, starting at postoperative day 1 until postoperative day 7.
4) In order to quantify intestinal tissue concentrations of the potential markers, a small part (distal 2 cm) of the tissue specimen that is removed for medical reasons, is stored at -80, and will be analyzed later on.

Study burden and risks

Voor de studie zal per patiënt 8 maal (veneus) bloed worden afgenomen. Minimaal 2 afnames hiervan zullen al gebeuren ten behoeve van de reguliere zorg. De belasting en het risico van deze venapuncties is minimaal.
Voor de studie zal 7 dagen postoperatief rectaal een tampon worden ingebracht (ongeveer 8 uur per dag). Het betreft een dunne tampon (ongeveer 1,5 cm doorsnede). Het risico hiervan is minimaal, de belasting voor de patiënt kan variëren van minimaal tot matig.

Venapunction is performed 8 times in each patient. At least 2 of these would have been done for regular healthcare purposes. Minimal burden and risks is associated with these venapunctions.
Daily insertion of a cotton roll in the rectum is performed daily during 7 days (about 8 hours a day in situ). Minimal risk is associated with this procedure and the burden per patient is considered minimal to moderate.

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

Surgery for colorectal malignancy
Primary anastomosis

Exclusion criteria

Inflammatory bowel disease, infectious co-morbidities of the gut.

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):	01-04-2011
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO

Date:	20-12-2010
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	NL34500.096.10