

# Immune Monitoring after Colorectal Surgery

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON27730

### Source

Nationaal Trial Register

### Brief title

IMACS

### Health condition

Postoperative infectious complications that occur within 30 days after surgery.

- Colorectal Anastomotic Leakage (CAL)
- Intra-abdominal abscess
- Sepsis
- Urinary Tract Infection (UTI)
- Pneumonia
- Surgical Site Infection (SSI)

## Sponsors and support

**Primary sponsor:** Erasmus Medical Center

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**Source(s) of monetary or material Support:** Sofradim Production, a Medtronic plc company, having a place of business at 116 avenue du Formans, Trevoux, France 01600

## Intervention

## Outcome measures

### Primary outcome

Postoperative infectious complications that occur before and/or at presentation at first outpatient department visit, or within 30 days after surgery.

#### - Colorectal Anastomotic Leakage (CAL)

We defined CAL as an insufficiency of the anastomosis, demonstrated by either endoscopy, CT-scan and/or (water-soluble) contrast enema or re-operation(39).

#### - Intra-abdominal abscess

Intra-abdominal abscesses demonstrated by imaging studies or with the need to be verified by either surgical drainage or by ultrasonographically, or CT guided aspiration of pus.

#### - Sepsis

Sepsis was defined by clinical symptoms, if possible combined with a positive blood culture.

#### - Urinary Tract Infection (UTI)

UTI was defined by a positive urine culture and/or requirement of antibiotic treatment.

#### - Pneumonia

Pneumonia was defined by a positive X-ray and/or requirement of antibiotic treatment.

- Surgical Site Infection (SSI)

SSI is defined as the presence of pus, either discharged spontaneously or requiring drainage, at the surgical site.

### **Secondary outcome**

Not applicable

## **Study description**

### **Background summary**

Rationale: Our hypothesis is that infectious stimuli lead to a marker profile of neutrophils and monocytes that allows the distinction of patients with increased risk of infectious complications from those without, despite the general inflammatory state induced by the surgical procedure.

Objective: To assess the predictive value of immune monitoring after colorectal surgery for early detection of postoperative infectious complications.

Study design: The IMACS study is a prospective pilot study that assesses the predictive value of immune monitoring after colorectal surgery for early detection of infectious complications. The expression of CD markers of myelomonocytic populations in peripheral blood will be determined with FACS analysis. A blood samples of 10 mL is required before surgery and 3 mL daily at the first three days after surgery.

Study population: The source population for this pilot study will be patients who undergo colorectal resection for malignancies. Patients who undergo Hemicolectomy Left, Hemicolectomy Right, Sigmoid Resection or Partial Mesorectal Excision (PME) / Total Mesorectal Excision (TME) will be eligible for inclusion.

Intervention (if applicable): Not applicable

Main study parameters/endpoints:

Postoperative infectious complications that occur within 30 days after surgery.

- Colorectal Anastomotic Leakage (CAL)

- Intra-abdominal abscess

- Sepsis

- Urinary Tract Infection (UTI)
- Pneumonia
- Surgical Site Infection (SSI)

### **Study objective**

Our hypothesis is that infectious stimuli lead to a marker profile of neutrophils and monocytes that allows the distinction of patients with increased risk of infectious complications from those without, despite the general inflammatory state induced by the surgical procedure.

### **Study design**

singel timepoint

### **Intervention**

blood collection

## **Contacts**

### **Public**

Erasmus Medical Center University  
Pim Edomskis

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### **Scientific**

Erasmus Medical Center University  
Pim Edomskis

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## **Eligibility criteria**

### **Inclusion criteria**

Patients who undergo Hemicolectomy Left, Hemicolectomy Right, Sigmoid Resection or Partial Mesorectal Excision (PME) / Total Mesorectal Excision (TME) will be eligible for inclusion.

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

- Informed Consent
- Primary anastomosis
- Colorectal carcinoma

## Exclusion criteria

- Age < 18 years
- Pregnancy
- Preoperative chemotherapy and/or radiotherapy
- Perioperative HIPEC treatment
- Inflammatory disease (i.e. inflammatory bowel disease, auto-immune deficiencies)
- Immunosuppressant drug use

## Study design

### Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	N/A: single arm study
Masking:	Open (masking not used)
Control:	N/A , unknown

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-08-2017
Enrollment:	50

Type: Anticipated

## IPD sharing statement

**Plan to share IPD:** Yes

## Ethics review

Positive opinion

Date: 29-10-2018

Application type: First submission

## Study registrations

### Followed up by the following (possibly more current) registration

ID: 49208

Bron: ToetsingOnline

Titel:

### Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

Register	ID
NTR-new	NL7369
NTR-old	NTR7577
CCMO	NL59261.078.16
OMON	NL-OMON49208

## Study results