

# Immune subset kinetics during abdominal surgery; identifying possible predictors for postoperative ileus

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To determine the kinetics of several immune cell subsets to evaluate the immune response to tissue damage and surgical manipulation caused by laparoscopic surgery. Additionally we aim to identify prognostic parameters for postoperative ileus, which...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Will not start
<b>Health condition type</b>	Gastrointestinal motility and defaecation conditions
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON45507

### Source

ToetsingOnline

### Brief title

INSPECTOR studie

### Condition

- Gastrointestinal motility and defaecation conditions
- Gastrointestinal therapeutic procedures

### Synonym

lack of postoperative peristalsis, postoperative ileus

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Erasmus MC, Universitair Medisch Centrum Rotterdam

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

voor consumables

## Intervention

**Keyword:** flowcytometry, immune monitoring, postoperative ileus, predictors

## Outcome measures

### Primary outcome

Absolute cell numbers of different leukocyte populations in peripheral blood.

The studied populations will consist of T-cells (both CD4+ and CD8+), B-cells, NK-cells, Neutrophils, Eosinophils, Basophils and monocytes.

### Secondary outcome

- Comparison of leukocyte subset kinetics between patients that got a (prolonged) postoperative ileus and those that didn't after elective laparoscopic hemi- or partial colectomy for malignancy.
- First bowel sound, tolerance of oral food intake, passage of defecation and passage of flatus after surgery
- Postoperative opioid consumption
- Patient characteristics: Date of birth, date of operation, age, sex, length, weight, BMI, ASA-score, diabetes mellitus, smoking status, alcohol abuse, preoperative medication use (antihypertensiva, antihypercholesterolemia, corticosteroids, anticoagulants, NSAID\*s), cardiac history, cardiac symptoms, peripheral arterial disease, pulmonary history, pulmonary symptoms, preoperative ileus, neoadjuvant radiotherapy, neoadjuvant chemo-radiation, bowel preparation, prophylactic antibiotics.
- Surgical characteristics: Type of surgery, anastomosis (type, primary, configuration, location, stapled/hand-sewed, omentoplasty), operation

indication, operation time, anaesthesia, intra-operative complications, blood loss, date of admission, date of discharge, duration of hospitalization, drain (place, type), stoma (place, type), donuts, air-leaking test (including outcome), surgeons (amount and expertise) and postoperative complications.

## Study description

### Background summary

Postoperative ileus (POI) is a transient impairment of bowel motility and is an important clinical problem that commonly arises after colorectal surgery and usually presents with intolerance of oral food intake, abdominal distension, nausea, vomiting, and absence of flatus and defecation. POI is considered to be a physiological response to the surgical procedure. However, in approximately 30% of patients POI is prolonged, causing a significant increase in patient pain and discomfort, morbidity, hospitalization days and health care costs. Both the innate and adaptive immune system have been shown to play an important role in the development of POI. Unravelling the interactions and kinetics of the involved leukocytes is of great importance to understand the mechanism underlying generalized impairment of gut motility after surgery. Therefore the aim of this study is to systematically investigate the immune response following abdominal surgery, through advanced and innovative multicolour (8-12-color) flow cytometry.

### Study objective

To determine the kinetics of several immune cell subsets to evaluate the immune response to tissue damage and surgical manipulation caused by laparoscopic surgery. Additionally we aim to identify prognostic parameters for postoperative ileus, which is caused by massive influx of immune cell subsets to the interstitium of the intestine.

### Study design

Proof of concept/pilot prospective cohort study

### Study burden and risks

There is no serious extra risk for a patient that is participating in this trial and no potential benefit from participating. Venepuncture risks are

minimal.

## Contacts

### Public

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NL

### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- elective laparoscopic hemi- or partial colectomy with an anastomosis for colorectal carcinoma or elective laparoscopic liver resection for benign or oncological indication
- >18 years of age
- signed informed consent

### Exclusion criteria

- pre-existing immune deficiency
- use of immunosuppressant drugs
- previous colorectal resection or (chemo)radiation
- previous major liver surgery

## 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: 30

Type: Anticipated

## Ethics review

Approved WMO

Date: 31-08-2017

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	NL59338.078.16