Immune Monitoring after Colorectal Surgery

Published: 16-03-2017
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To assess the predictive value of immune monitoring after colorectal surgery for early detection of postoperative infectious complications.

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

Summary

ID

NL-OMON49208

Source
ToetsingOnline

Brief title
IMACS

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal therapeutic procedures

Synonym
Postoperative infectious complications after colorectal surgery

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus Universiteit Rotterdam
Source(s) of monetary or material Support: Bedrijf,Medtronic B.V.

Intervention

Keyword: Abdominal surgery, Early detection, Immune monitoring, Infectious complications

Outcome measures

Primary outcome

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)

Secondary outcome

Not applicable

Study description

Background summary

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 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. Participation requires daily venepuncture of 3 mL from day of surgery till the third postoperative day.

Study burden and risks

The extent of burden and risks associated with participation could be considered as small. The invasive procedure performed on behalf of the IMACS study is venepuncture (3 mL) performed at surgery and daily at the first three postoperative days. In case of standard clinical practice after colorectal surgery venepuncture is quite common to monitor the postoperative course. Whether venepuncture is performed during standard practice depends on the extent of patient*s recovery. Therefore the collection of blood samples on behalf of the IMACS study does not always includes extra venepuncture but sometimes 3 mL extra blood collection if venepuncture is indicated due to standard clinical practice.

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

- 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 invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	21-08-2017
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	16-03-2017
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	15-12-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	27-03-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	30-08-2019
Application type:	Amendment
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

ID: 27730
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL59261.078.16
Other	NTC7577
OMON	NL-OMON27730