Immune Monitoring after Colorectal Surgery

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	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
P.O. Box 2040, 3000 CA Rotterdam, The Netherlands, internal postal address Rg-2
Visiting address: office EE-173, Dr.Molewaterplein 40, 3015 GD Rotterdam, The Netherlands

Email p.edomskis@erasmusmc.nl | Telephone +31 10 704 36 83

www.erasmusmc.nl

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 myelomoncytic 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
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Scientific
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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:	Non controlled trial
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