

Immune Monitoring after Colorectal Surgery

Gepubliceerd: 29-10-2018 Laatste bijgewerkt: 19-03-2025

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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON27730

Bron

NTR

Verkorte titel

IMACS

Aandoening

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)

Ondersteuning

Primaire 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

Overige ondersteuning: Sofradim Production, a Medtronic plc company, having a place of business at 116 avenue du Formans, Trevoux, France 01600

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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)

Doel van het onderzoek

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.

Onderzoeksopzet

singel timepoint

Onderzoeksproduct en/of interventie

blood collection

Contactpersonen

Publiek

Erasmus Medical Center University
Pim Edomskis

0107043683

Wetenschappelijk

Erasmus Medical Center University
Pim Edomskis

0107043683

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-08-2017
Aantal proefpersonen:	50
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Ethische beoordeling

Positief advies

Datum: 29-10-2018

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 49208

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten