Deployment of a biobank for research and identification of biomarkers predicting postoperative Crohn*s disease recurrence: RAP-CD ancillary study

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Ethical review	Approved WMO
Status	Pending
Health condition type	Gastrointestinal inflammatory conditions
Study type	Observational invasive

Summary

ID

NL-OMON47935

Source
ToetsingOnline

Brief title
RAP-CD ancillary study

Condition

- Gastrointestinal inflammatory conditions

Synonym
Crohn's disease, inflammatory bowel disease

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Enterome bioscience

Intervention

Keyword: Biobank, Crohn's disease, Recurrence, Surgery

Outcome measures

Primary outcome

- The percentage of post-operative CD patients, colonized by FimH-expressing bacteria that aggregate with FimH blocker compound (EB8018/TAK018) at month 6 and the correlation with endoscopic recurrence, defined as Rutgeerts *i2 and/or intestinal inflammation necessitating start or switch of IBD medication within 12 months.

- Deployment of a biobank for future research into biomarkers and microbiota predicting postoperative recurrence

Secondary outcome

- Differences in the level of FimH+ bacteria in stool at baseline (preoperative) versus postsurgery

- Differences in adhesion, invasion and total levels of FimH+ bacteria measured in surgically resected tissue and biopsies sampled during colonoscopy.

- Correlation between risk factors for postoperative recurrence and level of FimH expressing bacteria

- Differences in the stool microbiome profile preoperatively versus postsurgeryand correlation with changes in biomarkers and in clinical and histologic data

Study description

Background summary

Bowel surgery rates in CD (Crohn*s Disease) patients are high, up to 50% within 10 years after diagnosis. The postoperative disease course is not fully understood and postoperative recurrence is common, despite different medical treatment options. More knowledge on the general postoperative disease course and predictors of postoperative recurrence would be highly valuable, so patients can be treated accordingly and postoperative recurrence rates may be lowered in this patient population.

Study objective

The aim of this exploratory study is to isolate and store blood samples, fecal samples, biopsies and fresh frozen resection specimen of CD patients undergoing bowel resection, for the identification of biomarkers predicting postoperative CD recurrence and for future research on postoperative CD disease course

Study design

A multicentre national observational study will be performed

Study burden and risks

There is no additional burden or risk for patients participating in this study. During the clinically indicated colonoscopies, extra biopsies will be taken. These biopsies carry a very low risk of complications. Furthermore, during clinically indicated blood sampling, an additional 30ml of blood will be obtained for research purposes. We do not anticipate complications from this procedure.

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

Crohn's disease patients of 18 years or older undergoing ileocolonic resection

Exclusion criteria

Patients not meeting the inclusion criteria and patients in whom no signed informed consent is obtained

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2019
Enrollment:	50
Type:	Anticipated

Ethics review

Approved WMO

Date:	17-07-2019
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	NL69975.078.19