Intestinal Microbial profiling by means of IS-pro: towards a novel biomarker for inflammatory bowel disease

Published: 29-10-2009
Last updated: 06-05-2024

Aim of this study is to analyse the microbiota, and its variation throughout time in patients with IBD with molecular microbial profiling techniques.

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

Summary

ID

NL-OMON47461

Source
ToetsingOnline

Brief title
MICROBE

Condition

- Gastrointestinal inflammatory conditions

Synonym
Crohn's disease, inflammatory bowel diseases, ulcerative colitis

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Crohn, microbial profiling, microbiota, ulcerative colitis

Outcome measures

Primary outcome

We expect to obtain proof of principle showing how the microbial composition of the intestine might be a biomarker for:

- subtypes of inflammatory bowel disease

- localization of inflammatory bowel disesase (as described in the Montreal classification)

- activity of inflammatory bowel disease, and a potential early indicator of exacerbation

Secondary outcome

IS-pro, a novel powerful molecular bacterial profiling method will be validated to be introduced as a new high-throughput approach to characterize the intestinal microbiota in a routine laboratory setting. This technique will be compared to novel molecular profiling techniques, such as 454 pyrosequencing or qPCR as gold standard of characterization of complex microbial communities.
For diagnostic application, profiles derived from standardized mucosal biopsy specimens will be compared to those derived from faecal samples and rectal swabs. With the comparison of these samples, we intend to verify the validity of faecal profiles as a proxy for mucosal profiles, thus providing a non-invasive diagnostic tool.

Study description

Background summary

The intestinal microbiota is implicated as an essential factor in the pathogenesis of IBD, although the exact role remains elusive. Consistent findings from the literature showed that the intestinal microbiota of patients with inflammatory bowel diseases (IBD) is different from that in healthy individuals and unstable over time. However, only very few patients are studied in-depth yet. In addition, results from the few studies currently available are difficult to compare due to differences in methodology e.g. different study populations or techniques used.
Since most intestinal bacteria are uncultivable, rapid, highly reproducible methods for high throughput bacterial profiling have been developed and optimised at our institute.

Study objective

Aim of this study is to analyse the microbiota, and its variation throughout time in patients with IBD with molecular microbial profiling techniques.

Study design

A prospective longitudinal observational study is conducted. Faecal samples and rectal swabs are collected at each visit to the outpatient clinic. A short questionnaire is conducted. Disease activity is determined according to standardized indices. Regular inflammation parameters are determined in blood samples and faecal samples. If patient is scheduled for regular colonoscopy during remission mucosal biopsy specimens are harvested. All samples are analysed with IS-pro and a subset of samples with 454 pyrosequencing and qPCR in order to obtain bacterial profiles. Stratification based on patient subgroups will be applied.

Study burden and risks

Participating patients are asked to collect a faecal sample and rectal swab each subsequent visit, with a maximum of six times. In case a regular diagnostic colonoscopy is performed mucosal biopsy specimens are harvested, besides the usual biopsy specimens for regular histologic examination.

Contacts

Public

Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1081HV
NL
Scientific
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1081HV
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Age 18 years to 70 years
* Informed Consent (IC)
* Established diagnosis of CD or UC for more than six months, based on clinical, endoscopic, radiologic and histologic characteristics

Exclusion criteria

* Use of antibiotics 1 month prior to the trial
* Extensive surgery for Crohn*s disease or ulcerative colitis*
* Recent myocardial infarction or unstable angina pectoris
* Suspected acute peritonitis or perforation
* Pregnancy
* Contraindications for harvesting biopsy specimens

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2010
Enrollment:	266
Type:	Actual

Ethics review

Approved WMO Date:	29-10-2009
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-06-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-08-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-05-2014
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-06-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-07-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-09-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-11-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-12-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL29131.029.09