Detection of FIT- , fecal- and mucosa-associated microbiome and microRNA in patients with suspected colorectal adenomas or cancer

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The primary objective of this study is to detect and analyse the microbiome and miRNA in patients with a positive FIT or with a suspicion of adenomas and colorectal cancer at the Erasmus MC.

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

Summary

ID

NL-OMON48887

Source
ToetsingOnline

Brief title
Microbiome and MicroRNA in patients with suspected CRC or adenomas.

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
Colorectal cancer; polyps

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Colorectal cancer, Faecal immunochemical test (FIT), Microbiome, MicroRNA

Outcome measures

Primary outcome

The main study parameter will be the analysis of the microbiome and miRNA in

relation to colorectal cancer and adenomas.

Secondary outcome

To assess the possibility of using the microbiome in a FIT as screening tool

for CRC

To assess the possibility of using miRNA panels in a FIT as screening tool for

CRC

To assess the difference in diversity and composition of the microbiome in FIT,

stool sample and mucosal biopsy

To assess the difference in diversity and composition of miRNA in FIT, stool

sample and mucosal biopsy

Study description

Background summary

Colorectal cancer (CRC) is one of the major causes of death in the Netherlands, accounting for almost 5000 deaths in 2014. As most CRCs may develop slowly over years from precursor lesions, screening and early diagnosis are key to disease prevention. Nowadays faecal immunochemical testing (FIT), a marker to detect human haemoglobin, is used as a screening tool for CRC. However, not all lesions bleed, and conversely, occult blood can on occasion be detected in fecal samples of otherwise healthy individuals. While the sensitivity of FIT tests for CRC is around 79%, its specificity for advanced adenomas is only 50%.

Thus, additional tools to identify individuals at risk for CRC, and to reduce the burden of unnecessary procedures, are called for. Recently, an association was made between the microbiome and carcinogenesis. This new development could lead to new markers for the screening of colorectal cancer. In addition, microRNA (MiRNA) seems to be a modulator in the tumour process as a result of their role in cell proliferation, differentiation and apoptosis, and have been suggested to be a stable, valuable biomarker for tumorigenesis.Until now, the majority of the studies assessed the microbiome and mircroRNA through faecal samples. However, mucosal tissue and luminal content show considerable differences in microbial composition. Furthermore, very little is known on microbiome and miRNA composition in FIT fluid.
The aim of the current study is to investigate whether or not the microbiome and miRNA can be detected in FIT samples, and function as additional biomarkers for CRC and adenomas. Secondly, we would like to evaluate whether or not the microbiome and miRNA differs in composition and diversity when analysed from FIT, faecal sample and mucosal samples.

Study objective

The primary objective of this study is to detect and analyse the microbiome and miRNA in patients with a positive FIT or with a suspicion of adenomas and colorectal cancer at the Erasmus MC.

Study design

Prospective cohort study

Study burden and risks

The additional burden for the patient is to provide two FITs, one stool sample and fill out one questionnaire. A FIT is a clean and easy method to probe faecal samples. No extra risks are associated for the participants associated with the study.

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

- Participants are between 50-75 years old.
- Positive FIT in national CRC screening program
- Suspicion of CRC
- Willing to collect two FIT samples, one stool sample from one stool and fill out one questionnaire

Exclusion criteria

- Unwilling or not able to give informed consent

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-10-2017
Enrollment:	160
Type:	Actual

Ethics review

Approved WMO Date:	17-05-2017
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	26-07-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	21-05-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	16-07-2019
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

No registrations found.

In other registers

Register	ID
CCMO	NL60941.078.17