Characterization of human and microbial genetic components in normal colon tissue, colorectal adenomas, saliva and fecal samples

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The primary objective of this study is the simultaneous characterization of human and microbiota genomic and transcriptomic components in healthy and adenoma mucosal samples as well as stool and saliva. In addition, microbiome shifts from normal...

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

Summary

ID

NL-OMON43246

Source
ToetsingOnline

Brief title
nvt

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
Colonic polyps, microbiome

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Janssen-Cilag,Janssen-Cilag/Janssen Prevention Center

Intervention

Keyword: Colorectal adenoma, Microbiome

Outcome measures

Primary outcome

The primary study endpoint is the composition and abundance of microbiota genomic and transcriptomic components in healthy and adenoma mucosal samples as well as stool and saliva.

Secondary outcome

The following secondary study parameters are designed to further compare the microbiome in normal and diseased tissues and matching stool and saliva and determine differences from patients with and without adenomas.

- Shifts in microbiome composition and abundance from normal mucosal to adenoma and its correlation with luminal and oral bacteria.

- Characterization of mechanisms through which microbiota cause or contribute to oncogenesis.

- Characterization of molecular sub-classification of polyps and its comparison to colon tumors.

- Identification of the presences of inflammation in the adenomas and its potential link with microbiome composition and abundance.

- Differences in transcriptomics and metatranstcriptomics (gene expression) of normal mucosa and adenomatous tissue.

- Characterize differences in composition and abundance of oral microbiota in

patients with and without adenomas by taking saliva samples of three different

oral mucosa locations.-

Study description

Background summary

Due to human the complexity of human gut microbiota and its implication in other gastrointestinal disorders, a potential pathogenic role for bacteria in CRC has been proposed for a long time, and more recently associations between bacteria and premalignant polyp development have also been found. Despite the advances made in this emerging field, most of the research conducted until now has studied human intestinal microflora from fecal samples. Interestingly, little is known about the potential correlation of gut microbiota with specific polyp and tumor host molecular features.

Study objective

The primary objective of this study is the simultaneous characterization of human and microbiota genomic and transcriptomic components in healthy and adenoma mucosal samples as well as stool and saliva. In addition, microbiome shifts from normal mucosa to polyp to adenocarcinoma and its correlation with luminal and oral bacteria, mechanisms through which microbiota cause or contribute to oncogenesis, molecular sub-classification of polyps, inflammation in polyps and its potential link with the microbiome will be further investigated. This study also aims to develop tools to analyse complex microbiome structures.

Study design

Cross-sectional study consisting of prospective tissue sampling of healthy colorectal biopsies, biopsies from adenomatous tissue and matched saliva and stool samples.

Study burden and risks

Prior to the colonoscopy three saliva samples and two fecal samples will be obtained from the participating patients. No additional risks are associated with the retrieval of these samples. During the colonoscopy additional biopsies will be taken from healthy colorectal tissue, and after polypectomy additional biopsies will be taken form the luminal side of the resected adenoma, and the risks associated with these biopsies are a minimal bleeding risk.

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

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
* Scheduled for a regular colonoscopy
* Aged 18 years or above
* Colonoscopy schedualed for one of the following indications:
o Positive FOBT (Fecal Occult Blood Test) outside of the national screening program for colorectal cancer
o Follow up after polypectomy or colorectal cancner
o Rectal blood loss or anemia
o Abdominal pain
o Familial history of colon cancer or adenoma
o Abnormal radiologic imaging of the colonsuch as barium enema or CT colonography

o Change in bowel habits
* Singed informed consent

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
* Previous surgical bowel resection, except from appendectomy
* Known or suspicion of inflammatory bowel disease.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-12-2016
Enrollment:	600
Type:	Actual

Ethics review

Approved WMO

Date:	20-10-2016
Application type:	First submission
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	NL57805.018.16