Determination of intestinal microbiota in faecal specimens and intestinal mucosa biopsy specimens using bacterial DNA-based profiling methods.

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Aim of this prospective study is to determine (temporal changes in) the intestinal microbiota in faecal specimens and microbiota adhering to the intestinal mucosa using bacterial DNA-based profiling methods.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON39196

Source
ToetsingOnline

Brief title
Determination of intestinal microbiota

Condition

- Other condition
- Gastrointestinal inflammatory conditions

Synonym
gut bacteria, intestinal microbiota

Health condition

obesitas

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: bacterial DNA, intestinal, microbiota, profiling

Outcome measures

Primary outcome

Primary outcome is a bacterial profile of the intestinal microbiota derived

from the inter spacer region PCR (IS-PCR) technique.

Secondary outcome

Faecal and mucosal profiles will be compared together, and with other DNA based

techniques.

Study description

Background summary

The human gut contains over 800 bacterial species in various concentrations. The total of bacteria in the bowel are called the intestinal microbiota. This microbiota plays an important role in health and disease. Diseases and disorders such as inflammatory bowel disease, irritable bowel syndrome, colorectal cancer and obesitas seems to be linked to a certain microbiome. In addition, the faecal microbiota fluctuates markedly in specific patient groups, whereas this fluctuation is less clear in healthy individuals. Temporal variation of mucosa-adherent microbiota (MAM) has hardly been studied. The characterization of the intestinal microbiota is possible with several DNA-based techniques including interspace region PCR profiling.

Study objective

Aim of this prospective study is to determine (temporal changes in) the

intestinal microbiota in faecal specimens and microbiota adhering to the intestinal mucosa using bacterial DNA-based profiling methods.

Study design

A cross-sectional study will be performed. A faecal sample will be collected before colonic cleansing. A questionnaire will be conducted. During colonoscopy residual faecal material will be collected and additional colonic mucosa biopsy specimens will be harvested besides usual samples for pathohistological examination. The samples will be analysed for the intestinal microbiota using DNA-based techniques. Stratification for patient subgroups will be applied.

Individuals undergoing subsequent colonoscopy are asked to collect additional faecal samples. An additional mucosal biopsy is harvested during following colonoscopy.

Study burden and risks

Participating patients are asked to collect a faecal specimen before colonic cleansing. This specimen will be collected at home. At the day of colonoscopy a questionnaire has to be filled in. Height and weight of the patient will be measured.
During colonoscopy two additional biopsy specimens, besides the usual amount of 4-6 biopsy specimens, will be harvested.

In case patient is planned for addtitional colonoscopy, he/she will be asked to collect three additional faecal samples. Two additional mucosal biopsy specimens will be harvested during re-colonoscopy.

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

Age 18 years and older
Informed Consent
Elective colonoscopy
Patient living within a 15km radius from the VUmc
Pre-endoscopy colonic cleansing with Kleanprep®

Exclusion criteria

Contraindication for colonoscopy
Contraindication for harvesting biopsy specimens
Other pre-endoscopy colonic cleansing than with Kleanprep®

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start
Start date (anticipated):	01-05-2008
Enrollment:	350
Type:	Anticipated

Ethics review

Approved WMO Date:	25-06-2008
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-06-2013
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	NL21085.029.07