Determination of intestinal microbiota in faecal specimens and intestinal mucosa biopsy specimens using bacterial DNAbased profiling methods.

Published: 25-06-2008 Last updated: 16-11-2024

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 DNAbased 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

2 - Determination of intestinal microbiota in faecal specimens and intestinal mucosa ... 4-05-2025

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 additional colonoscopy, he/she will be asked to collect three additional faecal samples. Two additional mucosal biopsy specimens will be harvested during re-colonoscopy.

Contacts

Public Vrije Universiteit Medisch Centrum

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

De Boelelaan 1117 Amsterdam 1081 HV NL

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 invasiveMasking:Open (masking not used)Control:UncontrolledPrimary purpose:Diagnostic

Recruitment

| NL | |
|---------------------------|----------------|
| Recruitment status: | Will not start |
| Start date (anticipated): | 01-05-2008 |
| Enrollment: | 350 |
| Туре: | 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 CCMO **ID** NL21085.029.07