Microbial communities in effluent of ileostomy subjects

Published: 07-12-2010
Last updated: 04-05-2024

The aim of this study is to determine the population and functionality dynamics of the microbiota in ileostomy subjects.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal conditions NEC
Study type	Observational non invasive

Summary

ID

NL-OMON34741

Source
ToetsingOnline

Brief title
Microbial communities in effluent of ileostomy subjects

Condition

- Gastrointestinal conditions NEC

Synonym
ileostomy patients

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Diversity, Functionality, GI tract Microbiota, Ileostomy effluent

Outcome measures

Primary outcome

From 20 ileostomy subjects the microbiota composition and functionality of their ileostomy effluent will be determined. In addition, questions on demographic characteristics and additional physical status (health) infomation will be included.

Secondary outcome

none

Study description

Background summary

Our gastrointestinal (GI) tract is inhabited by large numbers of microbes which collectively outnumber host cells by a factor of ten. The complexity of interactions between these microbes and our intestinal cells varies tremendously and includes pathogenic, competitive, and symbiotic interactions. Feces is the most easily available source of gastrointestinal (GI) tract material for microbial analysis, but since it represents the end station of the GI tract, it is not the most suitable source of material to get insight into the activity of GI tract microbes. Therefore, samples from ileostomy subjects are more promising since they provide insight into the ecology of the small intestine. The first preliminary studies with 5 healthy ileostomy subjects indicated that the diversity and population dynamics of the microbiota are completely distinct from those in the feces. This motivated us to study the diversity and also functionality of the microbiota in a larger number of ileostomy subjects.

Study objective

The aim of this study is to determine the population and functionality dynamics of the microbiota in ileostomy subjects.

Study design

This observation study focuses on studying the diversity and functionality of

microbial communities in the GI tract of ileostomy subjects.

Study burden and risks

Ileostomy effluent samples will be collected at home by the volunteers, sampling protocols and equipment (tubes) will be collected at home by the volunteers, sampling protocols and equipment (tubes) will be explained to volunteers, who will also be provided with a storage facility (polystyrene box of dry-ice). Samples will be collected by a research team representative. There are no risks concerning these procedures. In addition, a questionnaire concerning demographig characteristics and physiological status (health) information of the volunteers has to be completed.

Contacts

Public
Universitair Medisch Centrum Groningen

Postbus 30.001
9700 RB Groningen
NL
Scientific
Universitair Medisch Centrum Groningen

Postbus 30.001
9700 RB Groningen
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

patients with an ileostomy, otherwise healthy, 18 years and older, able to understand the study information and to give their independent informed consent.

Exclusion criteria

recent history (i.e. last month) or current use of medication that may affect the intestinal microbiota.
use of pre- and/or probiotics during the month before the collection of the fecal samples.
pre-existing small bowel diseases (except for stoma).
pregnancy/breast feeding.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2011
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	07-12-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL30824.042.09