The real distribution of microbiota along the colonic mucosa using a novel device capable of taking *protected* biopsies

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Primary Objective: to show the differences in distribution of microbial DNA proximal versus distal in the colon as well as luminal composition versus mucosa adherent. Secondary Objective: to test whether bowel lavage has influence on the microbial...

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

Summary

ID

NL-OMON38135

Source
ToetsingOnline

Brief title
protected biopsies to show colonic microbiota

Condition

- Gastrointestinal conditions NEC

Synonym
niet van toepassing

Research involving
Human

Sponsors and support

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

Intervention

Keyword: colon, HITChip, microbiota, protected biopsies

Outcome measures

Primary outcome

• Intra-individual differences in phylogenetic fingerprinting and phylotype quantification from mucosal and faecal biopsy samples located at the colon ascendens and the sigmoid both in an *ill prepared* as well as in a *well-prepared* situation

Secondary outcome

• Intra-individual differences in phylogenetic fingerprinting and phylotype quantification from mucosal and fecal biopsy samples located at the colon ascendens and sigmoid using *protected* biopsy material versus *un-protected* material.

Study description

Background summary

The human microbiota forms a highly complex ecosystem with its host, consisting of hundreds of different species of microorganisms, the majority of which have not yet been cultured. With the recent advent of small subunit rRNA (SSU rRNA) gene sequencing technology, it is now estimated that the cumulative number of specific gastrointestinal tract phylotypes is more than 1800, of which less than 25% can be identified with culture dependent approaches. It is not properly established whether there is a difference in distribution of luminal bacteria or mucosa adherent bacteria proximal or distal in the colon. In addition, *bowel lavage* before endoscopy might result in a disturbance of the microbiota in the bowel. Moreover, sampling techniques might constitute a major confounder in the read-out of highly sensitive techniques such as SSU-DNA analysis.
For this proof of concept study a novel device capable of taking *protected* biopsies has been designed.

We hypothesize that the distribution of mucosal and luminal microbiota changes from proximal to distal in the colon, and by taking *protected biopsies* there will be the opportunity to show the real distribution of microbiota according to the localisation in the colon.
Furthermore, we hypothesize that microbial diversity will differ after bowel lavage.

Study objective

Primary Objective: to show the differences in distribution of microbial DNA proximal versus distal in the colon as well as luminal composition versus mucosa adherent.
Secondary Objective: to test whether bowel lavage has influence on the microbial distribution in the bowel.

Study design

This is a proof of concept genuine exploratory study

Study burden and risks

There will be no direct benefit associated with participation.
The only extra risk associated to this protocol pertains to the extra biopsies. Biopsy sampling during colonoscopy is very safe. The only risk associated with this procedure is post biopsy bleeding. Significant bleeding as a result of taking biopsies is very rare.

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

Boston scale <3 during colonoscopy
Sufficient indication to perform colonoscopy again

Exclusion criteria

• Inability to give informed consent
• Life expectancy < 12 months
• Use of combination of two platelet aggregation inhibitors
• Mandatory use of anti-coagulatory medication
• Known history of hemostatic disorder
•Use of systemic antibiotics in preceding 6 weeks
•Use of probiotic or prebiotic treatment in preceding 6 weeks
•Positive stool cultures for common enteric pathogens (Salmonella, Shigella, Yersinia, Campylobacter, enteropathogenic e coli)
• History of surgery:
oResection of any part of the colon or Ileocoecal resection
oPresence of an ileo- or colostoma

Study design

Design

Study type:	Observational invasive
Intervention model:	Other

Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-11-2013
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	13-03-2012
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	NL35517.018.11