Linking fecal microbiota composition to anti-saccharomyces cerevisiae antibody (ASCA) production in inflammatory bowel disease (IBD)patients.

Published: 10-01-2018
Last updated: 12-04-2024

To investigate associations between IBD severity, ASCA titer, microbiota composition and C. albicans strains present in feces.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal inflammatory conditions
Study type	Observational non invasive

Summary

ID

NL-OMON44343

Source
ToetsingOnline

Brief title
Microbiota in inflammatory bowel disease

Condition

- Gastrointestinal inflammatory conditions

Synonym
intestinal inflammation

Research involving
Human

Sponsors and support

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

Intervention

Keyword: ASCA's, IBD, microbiota

Outcome measures

Primary outcome

1) A correlation in CD patiënts between C.albicans strains and ASCA titer in blood.

2) A correlation in CD patiënts between fecal microbial composition and ASCA titer in blood.

Secondary outcome

The secondary study parameters are based on a correlation between disease severity (measured by determination of fecal calprotectin) and fecal microbial composition/ fecal C.albicans strains in CD, UC and healthy volunteers.

Study description

Background summary

Various studies have suggested a role for fungi in IBD(1-3). 50% to 70% of Crohn*s Disease (CD) patients produce antibodies against the mannan component of fungi, called anti- saccharomyces cerevisiae antibodies (ASCA*s), and against other fungal antigens. Only 5-15% of the ulcerative colitis (UC) patients and 0-5% of healthy controls test positive for these antibodies. ASCA titer seems also related to disease severity in CD, suggesting that fungi are relevant for development of CD. A quarter of the intestinal fungal species are of the Candida genus. It has been shown that in IBD patients fungal diversity is reduced compared to healthy controls while the proportion of C. albicans is increased. Together, this suggests that C. albicans plays a role in intestinal inflammation in CD patients. C. albicans is a commensal fungus that can become pathogenic. Information on genetic diversity and dynamics of the C. albicans population and on the characteristics of C. albicans strains in healthy people and in patients is important in order to clarify the role of C. albicans in IBD. In collaboration with Prof. T. Broekhout (UVA and CBS-KNAW) we will carry out multilocus sequence typing (MLST) of C. albicans isolated from stool of IBD

patients and healthy volunteers. MLST is a characterization technique in which 7 housekeeping genes are sequenced and based on SNPs located in these genes 15.000 C. albicans strains can be characterized(9). Besides the MLST of C. albicans we will also perform 16S and 18S sequencing to map correlations with the overall microbiota and mycobiota, also blood will be analyzed for the presence of ASCA*s. Together this enables us to find correlations between C.albicans strains, disease and presences of ASCAs in IBD patients.

Study objective

To investigate associations between IBD severity, ASCA titer, microbiota composition and C. albicans strains present in feces.

Study design

observational study

Study burden and risks

This study is considered to be an observational study with a low patient risks, all subjects will undergo already established procedures which include one blood withdraw and handing of one faecal sample

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

For all groups:
- Age from 18 years, either male or female
- Ability to give informed consent
- No use of antibiotics or antifungals 3 months prior to sample collection. ;Group specific inclusion criteria:
- Group 1 and 2 the patients have been diagnosed with CD.
- Group 3 patients have been diagnosed with UC patients.
- Group 4 People have not been diagnosed with IBD.

Exclusion criteria

Inability to give informed consent

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-11-2018
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Date:	10-01-2018
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	NL63207.018.17