Diet and disease activity in patients with Inflammatory Bowel Disease

Published: 12-11-2012
Last updated: 26-04-2024

We aim to study the role of diet in IBD in 2 subprojects: A) to study the prevalence of malnutrition in a consecutive cohort of IBD outpatients and to validate a malnutrition screening tool for IBD; B) To study the association of dietary patterns...

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

Summary

ID

NL-OMON41711

Source
ToetsingOnline

Brief title
Diet and IBD

Condition

- Gastrointestinal inflammatory conditions

Synonym
colitis, IBD

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Diet, Inflammatory Bowel Disease, Microbiota

Outcome measures

Primary outcome

The main study parameters are the prevalence of malnutrition in a consecutive IBD outpatient cohort for part A and the identification of different dietary patterns in relation to disease activity in IBD for part B.

Secondary outcome

Part A

1.To study the prevalence of vitamin and or mineral deficiencies determined in blood samples in a consecutive cohort of IBD outpatients.

2.The study the association of disease characteristics and dietary intake with the prevalence of malnutrition in a consecutive cohort of IBD outpatients

3. To study the sensitivity and specificity of the SNAQ / MST as malnutrition screening tool in IBD outpatients based.

Part B

1.To characterize intestinal microbiota in IBD patients with different dietary patterns

2.To characterize the intestinal microbiota in IBD patients in remission developing an exacerbation during follow up

3.To investigate the stability of the intestinal microbiota in IBD patients remaining in remission during one year follow-up

4. The role of dietary intake on epigenetics in the development of

exacerbations among IBD patients

Study description

Background summary

In addition to a genetic susceptibility, the immune system and the intestinal microbiota, diet is hypothesized to be an important factor in the onset and progression of Inflammatory Bowel Diseases (IBD). Further insight in factors affecting disease activity may contribute to targeted interventions improving disease burden and healthcare costs for these patients. However, well-designed studies exploring the role of diet in the development of exacerbations are hardly available. Furthermore, a subgroup of patients suffers from malnutrition, although the exact prevalence is unknown since simple non-invasive screening tools have not been validated for IBD.

Study objective

We aim to study the role of diet in IBD in 2 subprojects: A) to study the prevalence of malnutrition in a consecutive cohort of IBD outpatients and to validate a malnutrition screening tool for IBD; B) To study the association of dietary patterns and intestinal microbiota composition with disease activit, and possible mechanisme in a consecutive cohort of IBD patients of the IBD-SL biobank cohort.

Study design

Part A is a cross-sectional cohort study (n=300) and part B is a prospective cohort study with a follow up of one year (n=600).

Study burden and risks

The population based IBD-SL cohort is an excellent cohort to assess malnutrition in IBD patients. Blood and fecal samples are taken for routine clinical care. A part of the fecal sample will be stored in de IBD-SL biobank cohort for microbiota analyses. One extra serum tube (10 ml) and plasma tube (8,5 ml) will be collected and stored in the biobank. At baseline questionnaires have to be completed (Food frequency questionnaire (FFQ), short nutritional assessment questionnaire (SNAQ), malnutrition screening tool (MST)) which will take about 35 minutes. Furthermore anthropometric measurements and a Bod Pod® are performed. These investigations take about 20-30 minutes.
No side effects are to be expected from these measurements. However entering the Bod Pod® may be somewhat claustrophobic to certain subjects, because of the relative small size of the test chamber. Subjects may experience small pressure

changes on the ears.
Patients are followed during one year. At every routine outpatient visit the results of blood and fecal samples collected for routine clinical care are gathered and stored in the IBD-SL biobank cohort. Standardized clinical activity scores are already registered for routine care by the gastroenterologist and will be extracted from the electronic patient files. No side effects are expected from these measurements

Contacts

Public
Medisch Universitair Ziekenhuis Maastricht

P. Debeyeplein 25
Maastricht 6202 AZ
NL
Scientific
Medisch Universitair Ziekenhuis Maastricht

P. Debeyeplein 25
Maastricht 6202 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. IBD patients, diagnosis based on clinical, endoscopic, histological and/or radiological criteria
2.18-75 years

3. participating IBD-SL biobank cohort

Exclusion criteria

Unable to provide informed consent

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-11-2012
Enrollment:	600
Type:	Actual

Ethics review

Approved WMO

Date:	12-11-2012
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	05-06-2014
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	28-10-2015
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL42101.068.12
Other	protocol wordt op clinicaltrial.gov geregistreerd