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

2 - Diet and disease activity in patients with Inflammatory Bowel Disease 21-06-2025

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

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

4 - Diet and disease activity in patients with Inflammatory Bowel Disease 21-06-2025

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 |
| Туре: | 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

5 - Diet and disease activity in patients with Inflammatory Bowel Disease 21-06-2025

| 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 |
|----------|---|
| ССМО | NL42101.068.12 |
| Other | protocol wordt op clinicaltrial.gov geregistreerd |