

Introduction of a Diet as add-on therapy for remission maintenance in IBD

Published: 16-02-2018

Last updated: 12-04-2024

We aim to assess the feasibility of a nutritional intervention as add-on treatment (next to standard medical treatment) in patients with IBD in remission. We will measure the effect of the nutritional intervention on symptoms, quality of life and...

Ethical review	Approved WMO
Status	Pending
Health condition type	Gastrointestinal inflammatory conditions
Study type	Interventional

Summary

ID

NL-OMON46767

Source

ToetsingOnline

Brief title

Diet and IBD in remission

Condition

- Gastrointestinal inflammatory conditions

Synonym

crohns disease, inflammatory bowel disease, ulcerative colitis

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: Stichting voeding leeft

Intervention

Keyword: crohn's disease, Diet, lifestyle, Ulcerative colitis

Outcome measures

Primary outcome

We aim to assess the feasibility of a nutritional intervention as add-on treatment (next to standard medical treatment) in patients with IBD in remission

Secondary outcome

Secondary objectives are to study the effect of the nutritional intervention program on:

1. Quality of life and Food related quality of life (FR-QoL)
2. Activity of IBD (as assessed using Harvey-Bradshaw index (HBI) or partial Mayo score (pMS) and fecal calprotectin)
3. Nutritional status and anthropometry (body weight, hand grip strength, waist-hip ratio)
4. CAP value (Fibroscan; liver fat content)
5. Immunological assessment of Th17/Treg balance in the peripheral blood of patients to assess effect of our lifestyle intervention program on the pro-inflammatory / anti-inflammatory balance in the peripheral blood of patients

And in a subset of patients:

6. AGE reader

Study description

Background summary

Diet is important to patients with IBD (consisting of Crohn's disease and ulcerative colitis) and many patients ask whether eating the right foods can make a difference for their disease. Although studies about diet and IBD are conflicting, chronic inflammation, impaired intestinal barrier function and microbial disturbances seen in IBD may be reduced by an anti-inflammatory diet. We propose to investigate a nutritional intervention that combines foods and nutrients with proven or plausible anti-inflammatory properties

Study objective

We aim to assess the feasibility of a nutritional intervention as add-on treatment (next to standard medical treatment) in patients with IBD in remission. We will measure the effect of the nutritional intervention on symptoms, quality of life and serum markers of inflammation.

Study design

Open label intervention pilot study to test the efficacy of using a nutritional intervention as add-on treatment in patients with IBD in remission.

Intervention

Patients will enter a nutritional intervention program, coordinated by Stichting voeding leeft. Control subjects will continue their regular diet.

Study burden and risks

The nutritional intervention program consists of group sessions (syllabus added to the dossier for the METC), advising and educating patients about a plant-based diet.

As a novel add on therapy for IBD in remission, it represents a safe approach which has expected general health benefits, such as reducing the risks for developing NAFLD and cardiovascular diseases in patients that would change their lifestyle for a prolonged period.

an extra amount of blood will be drawn and stored.

Contacts

Public

Leids Universitair Medisch Centrum

albinusdreef 2
Leiden 233ZA
NL
Scientific
Leids Universitair Medisch Centrum

albinusdreef 2
Leiden 233ZA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

All patients with IBD in remission (fecal calprotectin (fCAL) < 150 mg/g and SES-CD<5, or MAYO score <1) are eligible to participate.

Exclusion criteria

Patients unable or unwilling to provide informed consent. Stenosis associated with symptoms. Current healthy lifestyle (as there will be nothing to optimize using our nutritional intervention program).

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 16-03-2018

Enrollment: 80

Type: Anticipated

Ethics review

Approved WMO

Date: 16-02-2018

Application type: First submission

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

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

CCMO

ID

NL63643.058.17