Anti-inflammatory diet as add-on therapy in inflammatory bowel disease

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Gastrointestinal inflammatory conditions
Study type	Interventional

Summary

ID

NL-OMON46158

Source
ToetsingOnline

Brief title
INSIDE

Condition

- Gastrointestinal inflammatory conditions

Synonym
chronic inflammation of the colon, inflammatory bowel disease

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: Ministerie van OC&W,Eat2Move

Intervention

Keyword: Crohn's disease, inflammatory bowel disease, nutrition, ulcerative colitis

Outcome measures

Primary outcome

The main study parameter is inflammation measured by faecal calprotectin at the beginning and end of each period. Lower values represent less or absence of inflammation.

Secondary outcome

Secondary parameters are clinical disease activity measured by the Crohn's Disease Activity Index (CDAI) in Crohn's disease and the Simple Clinical Colitis Activity Index (SCCAI) in ulcerative colitis, inflammatory markers in blood (CRP, cytokines, whole blood count, ferritin and albumin) and quality of life measured by Inflammatory Bowel Disease Questionnaire (IBDQ).

Study description

Background summary

Several studies have tried to improve clinical outcomes in IBD by modifying the diet. Most studies have been unsuccessful, probably due to the focus on single foods or nutrients, such as dietary fibre, fatty acids or dairy, instead of the whole diet. We propose to use a different approach: minimizing the inflammatory potential of the diet by choosing foods and nutrients which have shown anti-inflammatory properties in observational and intervention studies.

Study objective

The primary objective is to assess the effect of an anti-inflammatory diet as add-on therapy on faecal calprotectin in patients with inflammatory bowel disease. Secondary objectives will be to assess the effect of the diet on clinical disease activity, inflammatory markers in blood and quality of life.

Study design

This study will have a one group pretest-posttest design. We propose to perform a 4-week intervention study preceded by a 4-week run-in period and followed by a 4-week follow-up period. All foods and drinks will be provided during the intervention period. Study subjects will follow their habitual diet during run-in and follow-up periods.

Intervention

The intervention will be an anti-inflammatory diet, rich in vegetables, fruits and grains, with small amounts of fish and dairy products. Tea and water are the preferred drinks. Red and processed meat, soft drinks and other processed foods will be avoided.

Study burden and risks

Subjects need to visit the research unit 24 times, 4 times for measurements and 20 times to have dinner and receive other meals packaged for consumption at home in the 4-week intervention period. During the 4 measurement visits, blood samples will be taken and subjects need to fill in questionnaires (CDAI/SCCAI, IBDQ). For these four visits they are asked to bring a faecal sample and at the first and last visit they also need to fill in a FFQ. During every 4-week period, subjects are asked to fill in a 24-hour dietary recall three times, so 9 times in total. Since the investigational treatment of this study consists of daily used and freely available food products, there are no direct risks for the subjects.

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

- Diagnosis of Crohn's disease or ulcerative colitis (total or left-sided colitis) made by gastroenterologist and histologically proven
- Between 18-75 years of age
- Mild disease activity based on CDAI * 150 or SCCAI * 3
- Stable medical therapy for * 2 months
- Signed informed consent

Exclusion criteria

- Unwilling or unable to visit the Human Nutrition Research Unit five times per week during the intervention period
- Unwilling to strictly follow a diet for four weeks
- Participation in another intervention study
- Adherence to a vegan lifestyle
- Intending to make lifestyle changes during the duration of the study
- History of total or partial bowel resection
- Use of biologicals (e.g. infliximab, adalimumab, golumimab, ustekinumab, vedolizumab)
- More supplement use than the recommended dietary allowance
- Not allowing to inform the treating gastroenterologist about the participation
- Being an employee or student of Wageningen University, division of Human Nutrition and Health

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO

Date:	04-12-2018
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)

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	NL67452.081.18