

The effect of prolonged and repeated moderate-intensity exercise on inflammation in patients with Inflammatory Bowel Disease.

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The primary objective is to investigate the effect of prolonged and repeated moderate intensity exercise on faecal calprotectin in patients with IBD. Secondary objectives will be to investigate the effect on inflammatory markers and clinical disease...

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

Summary

ID

NL-OMON48058

Source

ToetsingOnline

Brief title

IB4D study

Condition

- Gastrointestinal inflammatory conditions

Synonym

chronic inflammation of the colon, inflammatory bowel disease

Research involving

Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum

Source(s) of monetary or material Support: Eat2Move

Intervention

Keyword: Crohn's disease, Exercise, Inflammatory Bowel Disease, Ulcerative colitis

Outcome measures

Primary outcome

The main study parameter is the change in gastrointestinal inflammation measured by faecal calprotectin in the IBD subjects.

Secondary outcome

Secondary parameters are inflammatory markers in blood and clinical disease activity measured by Harvey Bradshaw Index (HBI) in Crohn's Disease and the Simple Clinical Colitis Activity Index (SCCAI) in ulcerative colitis.

Study description

Background summary

Despite the fact that several studies suggest a role for exercise in maintenance of remission and improving quality of life in IBD, patients often express their concern that physical activity will aggravate their disease. Indeed, most of the studies are based on short exercise bouts or low intensity exercise and often lack objective markers of inflammation. More insight in the effect of prolonged and repeated exercise is necessary to provide patients with sound advice.

Study objective

The primary objective is to investigate the effect of prolonged and repeated moderate intensity exercise on faecal calprotectin in patients with IBD. Secondary objectives will be to investigate the effect on inflammatory markers and clinical disease activity.

Study design

This observational study will take place during the Nijmegen Four Days Marches

(NFDM) (July 16, 2019 * July 19, 2019).

Study burden and risks

Subjects need to visit the research unit five times during the NFDM for measurements. Five times blood samples will be taken and three times they are asked to bring a faecal sample. Additionally, they need to fill in online questionnaires. Since this is an observational study, the additional risk for the subjects is minimal.

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- 18 years of age or older (all participants)
- Diagnosis of Crohn's disease or ulcerative colitis (total or left-sided colitis) made by gastroenterologist (IBD participants)
- Participation in Nijmegen Four Day Marches, edition 2019 (all participants)

Exclusion criteria

- Use of biologicals (e.g. infliximab, adalimumab, golumimab, ustekinumab) (IBD participants)
- History of IBD or other gastro-intestinal diseases such as celiac disease or Irritable Bowel Syndrome (IBS) (healthy participants)
- History of significant systemic diseases, such as diabetes mellitus, cancer, cardiovascular or respiratory disease, that may have an effect on study outcomes (healthy participants)

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	14-07-2019
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date: 19-06-2019
Application type: First submission
Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 27563
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL69804.091.19
OMON	NL-OMON27563

Study results

Date completed: 17-12-2019
Actual enrolment: 38