

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

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	-
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON27563

### Source

Nationaal Trial Register

### Brief title

IB4D

### Health condition

Inflammatory Bowel Disease; Crohn's disease; Ulcerative Colitis

## Sponsors and support

**Primary sponsor:** Wageningen University / Radboudumc, Nijmegen

**Source(s) of monetary or material Support:** Eat2Move

## Intervention

## Outcome measures

### Primary outcome

Change in gastrointestinal inflammation measured by faecal calprotectin.

## Secondary outcome

Changes in:

- Inflammatory markers in blood
- Clinical disease activity

## Study description

### Background summary

**Rationale:** 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.

**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 population:** The study population will consist of two groups of each 20 adults. The first group will consist of subjects diagnosed with histologically proven Crohn's disease or ulcerative colitis, total or left-sided, who participate in the NFDM. The second group will consist of healthy subjects participating in the NFDM.

**Main study parameters/endpoints:** The main study parameter is the change in gastrointestinal inflammation measured by faecal calprotectin in the IBD subjects. More general inflammatory markers will be measured in both groups to distinguish between disease effects and exercise effects.

### Study objective

Our hypothesis is that prolonged and repeated exercise is safe for IBD patients and will therefore not lead to a clinically relevant increase of inflammation. Moreover, we think that acute effects on inflammatory markers are comparable between IBD patients and healthy controls.

### Study design

Change in faecal calprotectin: 3 time points

Change in inflammatory markers in blood: 5 time points

Change in clinical disease activity: 2 time points

## **Intervention**

N/A

## **Contacts**

### **Public**

Wageningen University

Carlijn Lamers

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### **Scientific**

Wageningen University

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## **Eligibility criteria**

### **Inclusion criteria**

IBD subjects:

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

Healthy subjects:

- 18 years of age or older
- Participation in Nijmegen Four Day Marches, edition 2019

### **Exclusion criteria**

IBD subjects:

- Use of biologicals (e.g. infliximab, adalimumab, golumimab, ustekinumab)

Healthy subjects:

- History of IBD or other gastro-intestinal diseases such as celiac disease or Irritable Bowel Syndrome (IBS)
- History of significant systemic diseases, such as diabetes mellitus, cancer, cardiovascular or respiratory disease, that may have an effect on study outcomes

## Study design

### Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Active

### Recruitment

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

### IPD sharing statement

**Plan to share IPD:** No

#### Plan description

N/A

## Ethics review

Positive opinion	
Date:	13-07-2019
Application type:	First submission

## Study registrations

### Followed up by the following (possibly more current) registration

ID: 48058

Bron: ToetsingOnline

Titel:

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

No registrations found.

### In other registers

Register	ID
NTR-new	NL7872
CCMO	NL69804.091.19
OMON	NL-OMON48058

## Study results

### Summary results

N/A