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

Gepubliceerd: 13-07-2019 Laatst bijgewerkt: 19-03-2025

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Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON27563

Bron
Nationaal Trial Register

Verkorte titel
IB4D

Aandoening

Inflammatory Bowel Disease; Crohn's disease; Ulcerative Colitis

Ondersteuning

Primaire sponsor: Wageningen University / Radboudumc, Nijmegen
Overige ondersteuning: Eat2Move

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Change in gastrointestinal inflammation measured by faecal calprotectin.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

Change in faecal calprotectin: 3 time points

Change in inflammatory markers in blood: 5 time points
Change in clinical disease activity: 2 time points

Onderzoeksproduct en/of interventie

N/A

Contactpersonen

Publiek

Wageningen University
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Wetenschappelijk

Wageningen University
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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	14-07-2019
Aantal proefpersonen:	40
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Toelichting
N/A

Ethische beoordeling

Positief advies

Datum:	13-07-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 48058
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A