Probiotica against fatigue in IBD

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Subjects randomized to the probiotics group will have a lower score on the Chalder Fatigue Questionnaire after 12 weeks of treatment compared to the placebo group.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28957

Bron
NTR

Verkorte titel
PAF

Aandoening

Crohn's Disease or Ulcerative Colitis

Ondersteuning

Primaire sponsor: Winclove B.V.
Overige ondersteuning: Not Applicable

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The difference in fatigue as measured by the Chalder Fatigue Questionnaire (CFQ) between the probiotics and placebo group.

Toelichting onderzoek

Achtergrond van het onderzoek

RCT to investigate the efficacy of probiotic supplementation after 12 weeks of treatment on symptoms of fatigue in subjects with Inflammatory Bowel Disease.

Doel van het onderzoek

Subjects randomized to the probiotics group will have a lower score on the Chalder Fatigue Questionnaire after 12 weeks of treatment compared to the placebo group.

Onderzoeksopzet

Week 0, 4, 8 and 12.

Onderzoeksproduct en/of interventie

Group A will daily receive 4 grams (2,5*109 cfu/gram) of the probiotic supplement Ecologic® BARRIER for the period of 12 weeks. Group B will be randomized to receive 4 grams of the placebo, identical in appearance, for the period of 12 weeks.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Subjects between the ages of 18 and 65 years old.
Subjects diagnosed with Crohn’s disease or Ulcerative Colitis.
Subjects with a score of 4 or higher on the Chalder Fatigue Questionnaire.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Subjects with active inflammation. Disease has to be in remission defined as CRP ≤ 10 mg/l, leucocytes between 4.0-10.0 10E9/l and calprotectin levels of ≤ 100 µg/g.
Subjects with abnormal laboratory values, including but not limited to hemoglobin, vitamin B12 and folic acid levels. These need to be corrected and retested before entering the study.
Subjects who used probiotics (including probiotic-containing products such as Yakult, Actimel, etc), antibiotics or Non-Steroidal Anti- Inflammatory Drugs (NSAIDs) in the 4 weeks prior to the screening visit, or are planning to do so during the study.
Subjects with local manifestation of IBD for which surgery might be indicated or which could confound the evaluation of efficacy.
Subjects who have had placement of a stoma or pouch.
Subjects who are pregnant, lactating or planning pregnancy while enrolled in the study.
Subjects who are unsuitable for inclusion in the study in the opinion of the investigator for any reason that may compromise the subject’s safety or confound data interpretation.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	20-01-2020

Aantal proefpersonen:	230
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	28-01-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 55158
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8334
CCMO	NL70721.028.19
OMON	NL-OMON55158

Resultaten