Probiotica against fatigue in IBD

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28957

Source
NTR

Brief title
PAF

Health condition

Crohn's Disease or Ulcerative Colitis

Sponsors and support

Primary sponsor: Winclove B.V.
Source(s) of monetary or material Support: Not Applicable

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

The differences in QoL indicated by the Inflammatory Bowel Disease Questionnaire (IBDQ) and the EuroQoL 5D questionnaire (EQ-5D), sleep quality examined by the Pittsburgh Sleep

Quality Index (PSQI), stool frequency and - consistency measured by the Bristol Stool Scale (BSS) and standard clinical laboratory assessments.

Study description

Background summary

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

Study objective

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.

Study design

Week 0, 4, 8 and 12.

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	20-01-2020
Enrollment:	230
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	28-01-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 55158
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

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

Study results