A randomized controlled trial to investigate the efficacy of a multispecies probiotic supplement (Ecologic® BARRIER) on symptoms of fatigue in subjects with Inflammatory Bowel Disease

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To evaluate the efficacy of a multispecies probiotics (Ecologic® BARRIER) for 12 weeks of intervention, compared with placebo on symptoms of fatigue (as measured by the Chalder Fatigue Questionnaire (CFQ)) in patients with IBD.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal inflammatory conditions
Study type	Interventional

Summary

ID

NL-OMON55158

Source
ToetsingOnline

Brief title
Probiotics against fatigue in IBD

Condition

- Gastrointestinal inflammatory conditions

Synonym
chronic bowel inflammation, inflammatory bowel disease

Research involving

Human

Sponsors and support

Primary sponsor: Elisabeth-Tweesteden ziekenhuis
Source(s) of monetary or material Support: Industrie,Winclove Probiotics

Intervention

Keyword: Fatigue, Inflammatory Bowel Disease, Probiotic, Randomized Controlled Trial

Outcome measures

Primary outcome

The primary endpoint of this study is the difference in fatigue as measured by the Chalder Fatigue Questionnaire (CFQ) between the probiotics and placebo group.

Secondary outcome

The secondary endpoints of the study are 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

Current evidence about the exact cause of Inflammatory Bowel Disease (IBD) involves a lack of balance in the intestinal microbiota, an inappropriate immunologic response to the gut microbiota and/or a decreased intestinal barrier function. Because of this, interest in management of the disease with probiotics has grown markedly.
For patients with IBD, fatigue is one of the most commonly reported complaints and a strong predictor for quality of life (QoL). Like IBD, evidence suggests

that also fatigue might be related to microbiota changes. Although several beneficial effects of probiotics on gastrointestinal symptoms have been identified, little research has been done on the role of probiotics in fatigue, especially in IBD patients. Given the high prevalence of fatigue complaints of fatigue in IBD patients, research on possible treatments is of great importance.

Study objective

To evaluate the efficacy of a multispecies probiotics (Ecologic® BARRIER) for 12 weeks of intervention, compared with placebo on symptoms of fatigue (as measured by the Chalder Fatigue Questionnaire (CFQ)) in patients with IBD.

Study design

Single-center, randomized, double-blinded, placebo-controlled, clinical trial to evaluate the efficacy of multispecies probiotics (Ecologic® BARRIER), versus placebo on symptoms of fatigue in subjects with Crohn*s disease (CD) or ulcerative colitis (UC). Subjects will be stratified for disease and then randomly assigned in a 1:1 ratio to receive probiotics or placebo.

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.

Study burden and risks

Subjects will be asked to fill out the above mentioned questionnaires as indicated by the table of assessments at the start of the study, after 4 and 8 weeks of supplementation and after 12 weeks of intervention. Furthermore, daily practice laboratory assessments will be collected during the study, as being part of the regular visits of these subjects. Probiotics' side effects, if they occur, tend to be mild and digestive, like flatulence or bloating, primarily in the first week of use.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Subjects between the ages of 18 and 75 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

- active inflammation
- abnormal labvalus
- use of prohbited medication
- stoma or pouch

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-01-2020
Enrollment:	220
Type:	Actual

Ethics review

Approved WMO Date:	28-10-2019
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	07-05-2021
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	18-10-2021
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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: 28957
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL70721.028.19
OMON	NL-OMON28957