Effect of dietary therapy with a probiotic mixture (Ecologic BARRIER) on the gut microbiome and fatigue symptoms in patients with quiescent inflammatory bowel disease - A clinical trial

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To evaluate the effect of dietary therapy with a probiotic supplement on the composition of stool microbiome in fatigued IBD patients with quiescent diseaseTo define the effect of dietary therapy with a probiotic supplement on serum inflammatory...

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

Summary

ID

NL-OMON46575

Source
ToetsingOnline

Brief title
Probiotic therapy in Inflammatory bowel disease

Condition

- Gastrointestinal inflammatory conditions

Synonym
Crohn's Disease, Inflammatory bowel disease, Ulcerative colitis

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Stichting Leveronderzoek financiert

Intervention

Keyword: Crohn's disease, Fatigue, IBD, Probiotic therapy, Quiescent disease, Ulcerative Colitis

Outcome measures

Primary outcome

Changes in fatigue symptoms after probiotic supplement

Secondary outcome

1. The feasibility of probiotic therapy in IBD patients

2. Changes in composition of stool microbiome, serum inflammatory cytokines and

metabolomic profiles after probiotic supplement

3.Changes in subjective symptoms like depression, anxiety and sleep after

probiotic supplement

Study description

Background summary

Nearly 48% of patients with quiescent inflammatory bowel diseases (IBD) suffer from severe fatigue which negatively impacts health-related quality of life. The mechanisms underlying fatigue in this population are poorly understood, limiting our ability to provide effective interventions. Existing therapies focusing on cognitive behavioral therapy have not been effective. Emerging research supports a role for the gut microbiome in mediating fatigue through several mechanisms including altered metabolism and the gut-brain axis. No prior studies have examined this in patients with IBD. Identification of a role for the microbiome in fatigue in IBD will offer new treatment targets to relieve fatigue.

The objective of the proposed project is to examine the role of the gut

microbiome in mediating fatigue in IBD through a prospective interventional treatment study.

Study objective

To evaluate the effect of dietary therapy with a probiotic supplement on the composition of stool microbiome in fatigued IBD patients with quiescent disease

To define the effect of dietary therapy with a probiotic supplement on serum inflammatory cytokines level and metabolomic profiles in fatigued IBD patients with quiescent disease

To assess the efficacy of a probiotic supplement on fatigue symptoms in patients with quiescent IBD.

Study design

Double blind randomized placebo-controlled clinical trial

Intervention

The study intervention for this clinical trial are probiotic supplements or placebo. Both the probiotic supplement and identical placebo. The probiotic supplements contains 9 different strains of bacteria and will be dosed in two dosages per a total of 40 billion bacteria daily for 12 weeks.The probiotic supplement is powder which can be diluted in some lukewarm water.

Study burden and risks

They study entails 4 study visits and 1 phone call which will be tried to combine with their routine clinical visits. During these visits, the subject will fill in questionnaires. We do not anticipate any psychosocial risks. At start and at the end of the study, the subject will be asked for a blood and stool sample.

The knowledge gained from this proposal will provide critical insight into effect of probiotic supplements on subjective symptoms, serum cytokine and metabolomic profiles, and the gut microbiome in patients with quiescent IBD. Our findings will significantly advance efforts towards identification of safe and effective therapies for fatigue in IBD.

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

* Age 18-75 years
* Confirmed CD or UC or IBD-unspecified diagnosed according to standard criteria
* Quiescent disease defined as HBI * 4 for CD and SCCAI * 2 for UC
* Persistent ongoing fatigue symptoms, defined as FACIT-F < 43
* Normal fecal calprotectin (< 250ug/g) and C-reactive protein (< 8mg/L) within 12 months of screening
* Endoscopic or radiologic remission within 12 months of screening

Exclusion criteria

* Patients with clinical or endoscopically active inflammatory bowel disease
* Significant non-IBD comorbidity contributing to the fatigue (such as active cancer).
* Untreated severe depression or anxiety
* Known sleep disorders without adequate treatment,
* Concurrent use of narcotics or long-term oral antibiotic therapy

* Severe vitamin D deficiency (< 10 ng/mL)
* J-pouch or a stoma
* Ongoing use of other non-study probiotics
* Women who are pregnant or lactating

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2018
Enrollment:	60
Type:	Anticipated

Ethics review

Approved WMO

Date:	16-11-2018
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT03266484
CCMO	NL65206.078.18