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Effect of Biotra ® on gut health

Submission date 02/02/2026	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 10/02/2026	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 10/02/2026	**Condition category** Digestive System	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
Constipation and poor bowel function are common gut health problems that can affect quality of life. Biotra® is a dietary supplement combining probiotics and fermented seaweed polyphenols, designed to improve gut microbiota activity and digestive regularity. This study aimed to evaluate whether Biotra® improves bowel habits and inflammation compared with placebo.

Who can participate?
Adults aged 21–65 years with symptoms of functional constipation meeting Rome III criteria, with BMI <35 kg/m².

What does the study involve?
Participants were randomly assigned to receive either Biotra® or placebo for 4 weeks. They took capsules daily (two at night, one in the morning). Bowel movement frequency and stool consistency were recorded, and biological samples were collected to assess inflammation and gut microbiota-related markers.

What are the possible benefits and risks of participating?
Possible benefits include improved bowel regularity, stool consistency, and reduced inflammatory markers. Risks were minimal, with adverse events monitored throughout the study period. Serious adverse events were to be reported within 24 hours.

Where is the study run from?
Medica Tokyo Laboratories (Japan)

When is the study starting and how long is it expected to run for?
The supplementation period lasted 4 weeks, with total participant involvement approximately 6 weeks including screening and follow-up.

Who is funding the study?
Innovation Labo, which provided and blinded the investigational product Biotra®

Who is the main contact?
Dr Yuki Ikeda, development@innovationlabo.com

Contact information

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Scientific

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Additional identifiers

Study information

Scientific Title
A prospective, randomized, double-blind, two-arm, parallel-group, placebo-controlled clinical trial to evaluate the efficacy of Biotra® supplementation on gut health parameters, including bowel movement frequency and stool consistency

Acronym
IL/NG 21-1228

Study objectives
The primary objective of this trial is to evaluate the effects of Biotra® supplementation on gut health parameters in adults with functional constipation, compared with placebo. Secondary objectives include assessing changes in fecal inflammatory markers, short-chain fatty acid (SCFA) levels, gut microbiota composition, and safety outcomes.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 12/11/2021, Japanese Society of Anti-Aging Nutrition (Ginza, Chuo-ku, Tokyo, 104-0061, Japan; +81 (0)3 3552 5277; coordinator@jaan.jp), ref: JAAN/GH 21-125

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Gut health

Interventions

Participants were randomized 1:1 to receive either:
1. Biotra® supplementation (active treatment) OR
2. Placebo (control group)
Both were administered orally daily (two at night, one in the morning) for 4 weeks in a double-blind parallel-group design.
Block randomization was used to allocate participants to each group.

Intervention Type
Supplement

Primary outcome(s)
1. Frequency of defecation measured using daily participant self-recorded bowel movement frequency (number of defecations per week) at baseline (week 0) and end of intervention (week 4)

2. Stool consistency measured using the Bristol Stool Consistency Chart (7-point scale) at baseline (week 0) and end of intervention (week 4)

Key secondary outcome(s)
1. Inflammatory marker malondialdehyde (MDA) measured using thiobarbituric acid reactive substances (TBARS) assay, measured by spectrophotometric detection as an index of lipid peroxidation and oxidative stress, at baseline (week 0) and end of intervention (week 4)

2. Fecal short-chain fatty acid (SCFA) levels measured using gas chromatography at baseline (Week 0) and week 4

3. Gut microbiota composition measured using quantitative PCR at baseline (week 0) and week 4

4. High-sensitivity C-reactive protein (hs-CRP) measured using ELISA assay at baseline (Week 0) and week 4

5. Total antioxidant capacity (TAC) measured using ferric reducing antioxidant power (FRAP) assay at baseline (Week 0) and week 4

Completion date
28/02/2022

Eligibility

Key inclusion criteria
1. Healthy adult men or women aged 21 to 65 years (inclusive)
2. Individuals with general symptoms of constipation who met the ROME III criteria for functional constipation
3. Body Mass Index (BMI) less than 35 kg/m²
4. Female participants of child-bearing potential were required to: Use an approved method of contraception, and have a negative pregnancy test at screening
5. Female participants of non-childbearing potential had to be amenorrheic for at least 1 year or have undergone hysterectomy and/or bilateral oophorectomy
6. Ability and willingness to provide written informed consent
7. Willingness to comply with all trial procedures and study visits

8. Ability to understand the potential risks and benefits of participation
9. Availability for the full study duration (approximately 6 weeks including follow-up)

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
21 Years

Upper age limit
65 Years

Sex
All

Total final enrolment
42

Key exclusion criteria
1. Constipation due to organic or neurological lesions
2. History of pathological bowel diseases, including inflammatory bowel disease (IBD) or colon cancer
3. Abnormal liver or renal function
4. Use of any prebiotic, probiotic, or laxative supplements within 4 weeks prior to study start
5. Use of antibiotics, anti-inflammatory, or immunosuppressive drugs within the past 4 weeks
6. Known allergy to soy milk or other ingredients of the test product
7. History of alcoholism or drug abuse
8. Pregnant or lactating women
9. History of anxiety, depression, or recent intake of psychotropic drugs
10. Any other medical or personal condition that, in the investigator’s opinion, could jeopardize the study outcomes

Date of first enrolment
10/01/2022

Date of final enrolment
31/01/2022

Locations

Countries of recruitment
Japan

Sponsor information

Organisation
Innovation Labo Sciences Co., Ltd

Funder(s)

Funder type

Funder Name
Innovation Labo Sciences Co., Ltd

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available