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Effects of OPTIMEALTH Food P 500 on gut health

Submission date	Recruitment status	[_] Prospectively registered
28/03/2025	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/05/2025	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
22/09/2025	Digestive System	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
The gut microbiota plays an important role in regulating human health and diseases. A growing body of knowledge supports the involvement of Gut microbiota dysbiosis in diseases such as diabetes, obesity, inflammatory bowel disease IBD and constipation. This study evaluates the efficacy of a postbiotic metabolite complex OPTIMEALTH Food P 500 developed by Innovation Labo, Tokyo. OPTIMEALTH Food P 500 was developed by studying the microbiota and health of healthy centenarians who have a particular microbiota profile. Innovation Labo discovered that the metabolites produced by the microbiota activate gene expression to inhibit and regulate inflammation and modulate the gut microbiome. The present study will evaluate the effect of OPTIMEALTH Food P 500 on constipation. To evaluate this, defecation frequency, stool consistency, constipation-related symptom scores, stool short-chain fatty acid (SCFA) content, gut microbiota composition and levels of oxidative biomarkers in blood will be measured.

Who can participate?
Non-smoking adult volunteers aged between 21 to 65 years old (inclusive) who have general symptoms of constipation and meet the ROME III criteria for functional constipation

What does the study involve?
Participants will be randomly assigned to a once-daily OPTIMEALTH FOOD P 500 supplement or a placebo/dummy supplement for 4 weeks.

What are the possible benefits and risks of participating?
Possible benefits are a reduction in constipation. No risk is expected.

Where is the study run from?
INNOVATION LABO Sciences Co., Ltd (Japan)

When is the study starting and how long is it expected to run for?
March 2023 to February 2024

Who is funding the study?
INNOVATION LABO Sciences Co., Ltd (Japan)

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

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
OF/GH /INNOVATION LABO 22-0421

Study information

Scientific Title
A prospective, randomized, double-blind, two-arm, parallel, placebo-controlled, clinical study to evaluate the efficacy of OPTIMEALTH Food P 500 supplementation on constipation symptoms, SCFAS content, and gut microbiota composition in healthy participants suffering from constipation

Study objectives
OPTIMEALTH Food P 500 is more efficient than a placebo in improving constipation symptoms, increasing short-chain fatty acid (SCFA) content and improving gut microbiota composition

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 17/03/2023, Swiss Association of Anti-Aging Nutrition Ethics Committee (Löwenstrasse, Zürich, 8001, Switzerland; +41 (0)79811 47 83; rfaber.saan@gmail.com), ref: 2023 /10-GFR105

Study design
Interventional double-blind placebo-controlled single-center randomized clinical trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Constipation

Interventions
This study investigates 4 weeks of daily supplementation with OPTIMEALTH Food P 500 (300 mg /day, 150 mg x 2 capsules) or a placebo (dextrin, 300 mg/day, 150 mg x 2 capsules) taken orally at breakfast. Block randomization was used to allocate participants to each group.

Block randomization is used to divide potential patients into m blocks of size 2n, randomize each block such that n patients are allocated to A and n to B then choose the blocks randomly. This method ensures equal treatment allocation within each block if the complete block is used.

Intervention Type
Supplement

Primary outcome(s)
Defecation frequency self-assessment measured using a daily chart at baseline and week 4

Key secondary outcome(s))
Current secondary outcome measures as of 22/09/2025:
The following secondary outcome measures are assessed at baseline and week 4:
1. Stool consistency by self-assessment measured using the Bristol stool chart at baseline and end of study period
2. Constipation-related symptom scores measured using a self-assessment questionnaire at baseline and end of study period
3. Stool short-chain fatty acid (SCFA) content measured using gas chromatography in fecal samples collected at baseline and end of study period.
4. Gut microbiota composition measured using 16sRNA analysis in fecal samples collected at baseline and end of study period.
5. Antioxidant activity is tested using enzymatic and chemical assays. Blood samples were collected at baseline and end of study period and analyzed for SOD, GPx and CAT along with Total Antioxidant Capacity.
6. Inflammatory markers in saliva samples analysed using ELISA at baseline and the end of the study period

Previous secondary outcome measures:
The following secondary outcome measures are assessed at baseline and week 4:
1. Stool consistency by self-assessment measured using the Bristol stool chart at baseline and end of study period
2. Constipation-related symptom scores measured using a self-assessment questionnaire at baseline and end of study period
3. Stool short-chain fatty acid (SCFA) content measured using gas chromatography in fecal samples collected at baseline and end of study period.
4. Gut microbiota composition measured using quantitative PCR in fecal samples collected at baseline and end of study period
5. Antioxidant activity is tested using enzymatic and chemical assays. Blood samples were collected at baseline and end of study period and analyzed for SOD, GPx and CAT along with Total Antioxidant Capacity.
6. Inflammatory markers in saliva samples analysed using ELISA at baseline and the end of the study period

Completion date
05/02/2024

Eligibility

Key inclusion criteria
1. Healthy adult male and female subjects between 21 to 65 years (inclusive) of age
2. Subjects with general symptoms of constipation and meet ROME IV criteria for functional constipation
3. Subjects with BMI between 18.5 and 29.9 kg/m²
4. Females of child-bearing potential must agree to use an approved form of birth control and to have a negative pregnancy test result at the screening visit. Female subjects of non-childbearing

potential must be amenorrheic for at least 1 year or had a hysterectomy and/or bilateral oophorectomy
5. Subjects must be willing to give written informed consent and be willing to comply with the trial protocol
6. Subjects must have the ability to understand the risks/benefits of the protocol
7. Subjects should be available for the total duration of the study period (6 weeks)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
21 years

Upper age limit
65 years

Sex
All

Total final enrolment
60

Key exclusion criteria
1. Subjects with constipation due to organic or neurological lesions
2. Subjects with a history of pathological bowel diseases like IBD or colon cancer
3. Subjects with abnormal liver or renal function
4. Subjects who have taken any prebiotic, probiotic or laxative supplements within 8 weeks of the start of the study period
5. Subjects receiving any antibiotic, antiinflammatory or immunosuppressive drug within the past 4 weeks
6. Subjects who have any known allergies to soy milk or any other ingredients of the test product
7. Alcoholics and drug abusers
8. Pregnant or lactating females
9. Subjects with a history of anxiety or depression or recent intake of psychotropic drugs
10. Any other condition that the Principal Investigator thinks may jeopardize the study outcome

Date of first enrolment
07/11/2023

Date of final enrolment
25/12/2023

Locations

Countries of recruitment
Switzerland

Study participating centre
Swiss Biome Institute
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Sponsor information

Organisation
INNOVATION LABO SCIENCES Co., Ltd

Funder(s)

Funder type
Industry

Funder Name
INNOVATION LABO Sciences Co., Ltd

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Yuki Ikeda, development@innovationlabo.com. Data will be available upon publication of results and for 2 years. Consent from participants was required and obtained. Data will be provided in an anonymised format.

IPD sharing plan summary
Available on request