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Efficacy of OPTIMEALTH FOOD on Gut health

Submission date 15/07/2024	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 05/08/2024	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 26/02/2025	**Condition category** Digestive System	[ ] Individual participant data [ ] 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 developed by Innovation Labo, Tokyo. OPTIMEALTH® FOOD P 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 on constipation. To evaluate this, parameters such as changes in defecation frequency, stool consistency, constipation-related symptom scores, changes in stool short-chain fatty acid (SCFA) content, gut microbiota composition and changes in levels of oxidative biomarkers in blood will be evaluated.

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

What does the study involve?
Participants will be randomly assigned to a once-daily OPTIMEALTH FOOD P 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?
January 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

Contact name
Dr Yuki Ikeda

ORCID ID
https://orcid.org/0000-0001-6067-4574

Contact details
Shintomi HJ bldg 5F
1-12-7 Shintomi
Tokyo
Japan
104-0041
+81 335525335
development@innovationlabo.com

Type(s)
Principal investigator

Contact name
Dr Taro Hirata

Contact details
14-5 Kusunokichō, Nishi-ku,
Yokohama-shi, Kanagawa-ken
Yokohama
Japan
220-0003
+81 335525335
coordinate@medica-labs.jp

Type(s)
Public

Contact name
Mrs Aki Honda

Contact details
Shintomi HJ bldg 5F
1-12-7 Shintomi
Tokyo
Japan
104-0041

+81 335525335
tokyo@innovationlabo.com

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

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

Study objectives
OPTIMEALTH FOOD P is more efficient than an placebo in improving constipation symptoms, increasing SCFAs content and improving gut microbiota composition

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 10/10/2023, Japanese Society of Anti-Aging Nutrition (Ginza, Chuo-ku, Tokyo, 104-0061, Japan; +81 3 3552 5277; coordinator@jaan.jp), ref: ILOS24614-P782

2. approved 17/10/2024, Swiss Association of Anti-aging Nutrition (Löwenstrasse 11, Zürich, 8001, Switzerland; +41 79 811 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
Improvement of constipation symptoms

Interventions

This study investigates 4 weeks of daily supplementation with Optimealth Food (300 mg/day, 150mg x 2 capsules) or a placebo (dextrin, 300 mg/day, 150mg 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))
The following secondary outcome measures are assessed at baseline and week 4:
1. Stool consistency by self-assessment measured using the Bristol stool chart
2. Constipation-related symptom scores measured using a self-assessment questionnaire
3. Stool short-chain fatty acid (SCFA) content measured using gas chromatography
4. Gut microbiota composition measured using quantitative PCR
5. Oxidative biomarker levels in blood measured using a ferric reducing antioxidant power (FRAP) assay

Completion date
05/02/2024

Eligibility

Key inclusion criteria
1. Healthy adult subjects between 21 and 65 years (inclusive) of age
2. General symptoms of constipation and meet ROME III criteria for functional constipation
3. 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. Willing to give written informed consent and be willing to comply with trial protocol
6. The ability to understand the risks/benefits of the protocol
7. Available for the 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. Constipation due to organic or neurological lesions
2. A history of pathological bowel diseases like IBD or colon cancer
3. Abnormal liver or renal function
4. Taken any prebiotic, probiotic or laxative supplements within 8 weeks from the start of the study period
5. Receiving any antibiotic, antiinflammatory or immunosuppressive drug within the past 4 weeks
6. Known allergies to soy milk or any other test product ingredients
7. Alcoholics and or drug abusers
8. Pregnant or lactating females
9. A history of anxiety or depression or recent intake of psychotropic drugs
10. Any other condition which 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
Japan

Switzerland

Study participating centre
Medica Tokyo Laboratories
14-5 Kusunokichō, Nishi-ku
Yokohama-shi
Kanagawa-ken
Yokohama
Japan
220-0003

Study participating centre
Swiss Biome Institute
Hegenheimermattweg 167A
Allschwil
Switzerland
4123

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. Anonymised IPD will be available upon publication of results and for a period of 2 years. Consent from participants was required and obtained.

IPD sharing plan summary
Available on request