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Evaluation of the efficacy of a food supplement in improving the regularity of bowel movements

Submission date 04/02/2026	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 17/02/2026	**Overall study status** Completed	
Last Edited 02/11/2026	**Condition category** Digestive System	

Plain English summary of protocol
Not provided at time of registration

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Additional identifiers

Clinical Study Protocol
EC_P0000958/25

Study Code_Order
H.E.HU.HV.NMS00.080.00.00_NT0001544-25

Study information

Scientific Title
Clinical evaluation of the efficacy of a food supplement in improving the regularity of bowel movements: a randomized, double-blind, parallel-group, placebo-controlled study

Study objectives
The primary objective of this study is to evaluate the efficacy of the product in improving the regularity of bowel movements in subjects with Irritable Bowel Syndrome with predominant diarrhea (IBS-D). The secondary objective of this study is to evaluate the efficacy and pleasantness of the product as perceived by the subjects.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 16/12/2025, International Ethics and Integrity Committee (Via Per Garbagnate 61, Lainate (MI), Lainate, 20045, Italy; +39 (0)3783037302; secretariat@ieicomittee.com), ref: Rif. IC011 A

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Parallel

Purpose
Treatment, Efficacy

Study type(s)

Health condition(s) or problem(s) studied

Irritable bowel syndrome with predominant diarrhea (IBS-D)

Interventions
The active product is a food supplement containing a multi-strain probiotic formulation (Serobioma), composed of Bifidobacterium longum BB536, Bifidobacterium lactis BL-04, and Lactobacillus rhamnosus LR-32, together with L-theanine, L-cystine, and vitamin B2, while the placebo contains the same excipients without the active ingredients.

A restricted randomization list will be generated by an independent technician using the appropriate algorithm (Wei's urn) of the PASS 11 software (PASS, LLC. Kaysville, UT, USA) and stored in a secure location. The Principal Investigator or designated personnel will dispense the products according to the generated randomization list: half of the subjects will be allocated to the active product and half of the subjects will be allocated to a placebo.

The study will be double-blind, meaning that subjects, the Principal Investigator and collaborators are kept masked to product assignment. The products will be supplied in the same packaging with no obvious differences between them.

Subjects will take the assigned treatment for 56 days ± 2 days as follows: one capsule after breakfast and one capsule after dinner, with a glass of water.

Intervention Type
Supplement

Primary outcome(s)
1. Number of bowel evacuation (n) measured using a diary at baseline, 28 and 56 days

2. Stool status measured using the Bristol Stool Form Scale (BSFS) (score from 1 to 7) at baseline, 28 and 56 days

Key secondary outcome(s)
1. Product acceptability measured using self-evaluation questionnaire (polytomous question with four possible answers) at 14, 28 and 56 days of product use

Completion date
11/09/2026

Eligibility

Key inclusion criteria
1. Healthy male and female subjects
2. Subjects of Caucasian ethnicity
3. Subjects aged between 18 and 64 years (extremes included)*
4. Subjects with Irritable Bowel Syndrome with predominant diarrhea (IBS-D)**
5. Subjects registered with national health service
6. Subjects certifying the truthfulness of the personal data disclosed to the investigator
7. Subjects able to understand the language used in the investigation center and the information given by the investigator
8. Subjects able to respect the instructions given by the investigator as well as able to respect the study constraints and specific requirements
9. Subjects who commit not to change their daily routine or lifestyle during the experimental

phase ***
10. Subjects on stable pharmacological therapy (except therapies listed under the non-inclusion criteria) for at least one month, with no changes expected or planned during the study
11. Subjects informed about the test procedures who have signed a consent form and privacy agreement

*If the subject is older than 50 years, they must have undergone a colonoscopy with a negative result within the previous 5 years

**Assessed by the gastroenterologist using Rome IV criteria diagnostic criteria for Irritable Bowel Syndrome: Recurrent abdominal pain on average at least 1 day per week in the last 3 months, with symptom onset at least 6 months prior to diagnosis (prior to the experimental phase. i.e washout period), associated with two or more of the following: related to defecation, associated with a change in frequency of stool, associated with a change in form (appearance) of stool
For the classification of the subtype Irritable Bowel Syndrome with predominant diarrhea (IBS-D): > ¼ (25%) of bowel movements with Bristol stool types 6 or 7; < ¼ (25%) of bowel movements with Bristol stool types 1 or 2.

***Subjects will keep a weekly diary where they will record their eating habits. This diary will be collected during the washout period and during the following weeks while taking the product.

Healthy volunteers allowed
Yes

Age group
Adult

Lower age limit
18 Years

Upper age limit
64 Years

Sex
All

Total final enrolment
88

Key exclusion criteria
1. Subjects who do not meet the inclusion criteria
2. Subjects with any acute, chronic, or progressive disease or condition that may interfere with the study data or that the investigator considers dangerous to the subject or incompatible with the requirements of the study****
3. Subjects participating or planning to participate in other clinical trials
4. Subjects who participated in a similar study without respecting an adequate washout period (at least one month)
5. Subjects who have food intolerances or food allergies to ingredients of the study product
6. Subjects under pharmacological treatments that are considered incompatible with the study requirement by the investigator*****

7. Subjects who are currently using food supplement(s) and/or products with the same activity as the study product, or who haven't observed an adequate washout period (at least one month)
8. Subjects admitted to a health or social facility
9. Subjects planning a hospitalization during the study
10. Subjects not able to be contacted in case of emergency
11. Subjects deprived of freedom by administrative or legal decision or under guardianship
12. Subjects who have or have had a history of alcohol or drug addiction
13. Subjects with eating disorders (i.e. bulimia, psychogenic eating disorders, etc.)
14. Subject breastfeeding, pregnant or not willing to take necessary precautions to avoid pregnancy during the study (for the women of childbearing potential)

****Including IBS-C, IBS-M, or IBS-U (according to the Rome IV criteria); alarm signs requiring further investigations (unexplained weight loss in the past 6 months, unexplained anemia, nocturnal symptoms, or blood in the stool except when due to hemorrhoids); inflammatory, autoimmune, or other organic gastrointestinal diseases (ulcerative colitis, Crohn’s disease, microscopic or ischemic colitis, celiac disease); intestinal infections; lactose intolerance; and any relevant organic, systemic, or metabolic conditions, as well as active malignant neoplasms or a history of malignancy with signs of recurrence within the previous 5 years.

*****Including major abdominal surgical procedures; use of probiotics or antibiotic therapy within the last month; frequent use of stimulant (contact) laxatives; incompatible pharmacological treatments (e.g., metformin, antihypertensive sartans, SSRI antidepressants).

Date of first enrolment
16/12/2025

Date of final enrolment
27/03/2026

Locations

Countries of recruitment
Italy

Study participating centre
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Sponsor information

Organisation
Bromatech SRL

Funder(s)

Funder type

Funder Name
Bromatech SRL

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available