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Clinical evaluation of the efficacy of a food supplement in improving the regularity of bowel movements

Submission date 13/03/2026	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 24/03/2026	**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 Number
EC_ NT0000023/26

Study Code_Order
H.E.HU.HV.NMS00.060.03.00_NT0000171-26

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 (increasing transit and motility) in subjects complaining of functional constipation. 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 02/03/2026, International Ethics and Integrity Committee (Via Per Garbagnate 61, Lainate (MI), Lainate, 20045, Italy; +39 (0)3783037302; secretariat@ieicomittee.com), ref: Rif. IC0017 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
Functional constipation

Interventions
The active intervention is a food supplement containing inulin (from chicory) powder, partially hydrolyzed guar gum, xanthan gum, a blend of acacia gum powder (Acacia seyal Delile, gummi) and dehydrated pulp of the fruit of baobab powder (Adansonia digitata L., fructus), Malva (Malva sylvestris L., folium) dry extract, maltodextrin from corn, α-gluco-oligosaccharide (α-GOS) powder, corn starch, natural flavor, cross-linked sodium carboxymethyl cellulose, and citric acid, while the placebo contains maltodextrin from corn, natural flavor and citric acid.

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 supplied with the active product, while the other half will be supplied with the 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.

The study is structured into two phases: a preliminary phase lasting 3 months and a 35-day experimental phase, which includes a 1-week washout period and 1 week of baseline data collection, followed by 21 days of treatment. Three clinical visits are planned during the preliminary phase and three clinical visits during the experimental phase at T0 (baseline visit), T14 (follow-up visit, after 14 ± 2 days of treatment), and T21 (final visit, after 21 ± 2 days of treatment).

Subjects take the assigned treatment for 21 days ± 2 days as follows: two sachets a day, one before breakfast and one before dinner. The product needs to be dissolved in water and drunk immediately or wait a few minutes and then be drunk.

Intervention Type
Supplement

Primary outcome(s)

1. Number of bowel evacuations (n) measured using a diary to record each movement at baseline and after 14 and 21 days of product use

2. Stool status measured using the Bristol Stool Form Scale (BSFS) (score from 1 to 7) at baseline and after 14 and 21 days of product use

Key secondary outcome(s)
1. Efficacy perceived and pleasantness of the product measured using self-evaluation questionnaire (polytomous question with four possible answers) at 14 and 21 days of product use

Completion date
17/09/2026

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 functional constipation**
5. Subjects registered with national health service
6. Subjects certifying the truthfulness of the personal data disclosed to the Principal Investigator or designated personnel
7. Subjects able to understand the language used in the investigation centre and the information given by the Principal Investigator or designated personnel
8. Subjects able to respect the instructions given by the Principal Investigator or designated personnel 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 study***
10. Subjects on stable pharmacological therapy (except for the pharmacological therapy in the non-inclusion criteria) for at least one month without any 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 functional constipation. To diagnose functional constipation, the individual must meet two or more of the following criteria for the last 3 months, with symptom onset at least 6 months prior to diagnosis:
1. Straining during more than ¼ (25%) of defecations
2. Lumpy or hard stools (Bristol Stool Form Scale 1-2) more than ¼ (25%) of defecations
3. Sensation of incomplete evacuation more than ¼ (25%) of defecations
4. Sensation of anorectal obstruction/blockage more than ¼ (25%) of defecations
5. Manual maneuvers to facilitate more than ¼ (25%) of defecations (e.g., digital evacuation, support of the pelvic floor)
6. Fewer than three spontaneous bowel movements per week
7. Loose stools are rarely present without the use of laxatives
8. Insufficient criteria for irritable bowel syndrome
***Subjects will keep a weekly diary where they will record their eating habits. This diary will be collected during the washout week 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
0

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 1 month)
5. Subjects that 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 1 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 organic constipation or another chronic digestive condition that could confound the evaluation of constipation (e.g. inflammatory bowel disease, neoplasia, intestinal obstruction); constipation secondary to chronic conditions such as metabolic, endocrine or neurological diseases; alarm symptoms (e.g., fever, gastrointestinal bleeding, weight loss, anemia, abdominal mass); or any condition considered by the principal investigator to interfere with the study. Verification will be performed by the principal investigator.
*****Including opioids, tricyclic antidepressants, monoamine oxidase inhibitors (MAOIs), anticonvulsants, calcium channel blockers, iron salts, calcium salts, aluminum salts, diuretics. Verification will be performed by the principal investigator.

Date of first enrolment
05/03/2026

Date of final enrolment
25/03/2026

Locations

Countries of recruitment
Italy

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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