ISRCTN11681307 https://doi.org/10.1186/ISRCTN11681307

The beneficial effect on gastrointestinal discomfort of a food supplement based on a mixture of tannins from Castanea sativa bark and Schinopsis quebracho-colorado wood

Submission date
08/10/2024

Recruitment status
No longer recruiting

Registration date
22/11/2024

Overall study status
Completed

Last Edited
21/01/2026

Condition category
Digestive System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Irritable Bowel Syndrome (IBS) is a chronic gastrointestinal disorder marked by symptoms such as abdominal pain, bloating, diarrhea, and altered bowel habits, affecting 5-15% of the Western population, particularly women under the age of 50. Diagnosis relies on symptom observation after ruling out other gastrointestinal (GI) disorders. The condition's pathophysiology involves factors like changes in GI motility, visceral hypersensitivity, small intestinal bacterial overgrowth (SIBO), dietary habits, and dysbiosis. Genetic variations, such as hypomorphic sucrase-isomaltase (SI), are linked to IBS-D symptoms. IBS is classified into primary (genetic) and secondary (duodenal villi atrophy/inflammation) forms, with subtypes including IBS-C (constipation-predominant), IBS-D (diarrhea-predominant), IBS-M (mixed bowel habits), and IBS-U (unclassified). Symptoms must occur at least once a week for three months. Tannins, found in botanicals like agrimony and strawberry leaves, are used for mild diarrhea and interact with gut microbiota, improving digestion, nutrient absorption, and stool consistency. This study aims to demonstrate the effects of a dietary supplement based on tannins from Castanea sativa Mill. bark and Schinopsis quebracho-colorado in managing GI symptoms and maintaining intestinal function balance in IBS patients.

Who can participate?
Patients aged between 18 and 70 years old with IBS, specifically those with IBS-C and(IBS-D

What does the study involve?
Patients will be randomly assigned to a treatment duration of 2 months with a daily food supplement or a placebo taken orally.

What are the possible benefits and risks of participating?
An improvement in the gastrointestinal symptoms and quality of life of the subjects treated with the food supplement is hypothesized. However, no benefit may be achieved. No risks are foreseen.

Where is the study run from?
COMEGEN General Practitioner's medical center, Italy

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

Who is funding the study?
INBB National Institute of Biostructures and Biosystems - Interuniversity Consortium

Who is the main contact?
1. Prof. Maria Daglia (scientific) maria.daglia@unina.it
2. Alessandra Baldi (public) alessandra.baldi.alimenti@gmail.com

Contact information

Type(s)
Scientific

Contact name
Prof Maria Daglia

ORCID ID
https://orcid.org/0000-0002-4870-7713

Contact details
University of Naples Federico II
Via Domenico Montesano, 49
Naples
Italy
800016
+39 3398177623
maria.daglia@unina.it

Type(s)
Public

Contact name
Ms Alessandra Baldi

ORCID ID
https://orcid.org/0000-0002-2877-9445

Contact details
INBB National Institute of Biostructures and Biosystems - Interuniversity Consortium, Viale delle Medaglie d'Oro, 305
Rome
Italy
00136
+39 3483854114
alessandra.baldi.alimenti@gmail.com

Type(s)
Principal investigator

Contact name
Dr Matteo Laringe

Contact details
Clinical Center COMEGEN, Viale Maria Bakunin, 41
Naples
Italy
80126
+39 3939406629
comegen@comegen.org

Additional identifiers

Study information

Scientific Title
Efficacy study of a food supplement based on a mixture of tannins from Castanea sativa Mill. Bark and Schinopsis quebracho-colorado (Schltdl.) F.A. Barkley & T. Mey wood for the management of gastrointestinal discomfort in subjects with irritable bowel syndrome (IBS): single-center, placebo-controlled, randomized clinical study, parallel arms, double-blind

Acronym
IBSTAN23

Study objectives
This study evaluates the efficacy of a dietary supplement containing tannins from Castanea sativa Mill. Bark and Schinopsis quebracho-colorado (Schltdl.) F.A. Barkley & T. Mey wood in improving gastrointestinal discomfort in subjects with irritable bowel syndrome (IBS), specifically those with predominant constipation (IBS-C) and diarrhea (IBS-D), and its impact on the quality of life.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 30/01/2024, Ethics Committee CAMPANIA 1 (Via Mariano Semmola, 53, Naples, 80131, Italy; +39 081/17770131; comitatoetico@istitutotumori.na.it), ref: Prot n° 5/23

Primary study design
Interventional

Study design
Interventional monocentric randomized parallel-group two-arm double-blind placebo-controlled trial

Study type(s)

Prevention

Health condition(s) or problem(s) studied
Subjects with irritable bowel syndrome (IBS), specifically those with predominant constipation (IBS-C) and diarrhea (IBS-D)

Interventions
The subjects recruited in the present clinical study have been randomized into the following experimental groups:
GROUP 1:
Subjects took two capsules of the dietary supplement, a mixture of tannins from Castanea sativa Mill. Bark and Schinopsis quebracho-colorado (Schltdl.) F.A. Barkley & T. Mey wood. The treatment consists of the dietary supplement Arbox Naturplus®, which was notified to the Italian Ministry of Health (notification number:101545). These were provided free of charge by the Interuniversity Consortium I.N.B.B., National Institute of Biostructures and Biosystems, Viale delle Medaglie d'Oro 305 - 00136 Rome, as the trial is no profit.
GROUP 2:
Subjects took the placebo.

The treatment period duration was 2 months.
All enrolled subjects were instructed and educated to drink at least 2 liters of water every day.

To maintain the double-blind design, the two treatments will be made unrecognizable as the packaging is identical, and the dosage forms are in the same color, shape, weight, and taste.

The randomization sequence has been generated by a statistician using STATA 16 software (Stata Statistical Software: Release 16. College Station, TX: StataCorp LLC) and the randomization list has been kept hidden. The participants were assigned to each of the two treatments randomly and unpredictably, through simple randomization. The randomization code will consist of a three-digit number as indicated in the respective Case Report Form (CRF).

Participants underwent two visits (at the start of the treatment period = t0, and at the end of the treatment period (56 days) = t1) in an outpatient setting. After each clinical visit, all data are filled in the CRF by physicians.
The clinical trial design is reported below:
T0. Start of the first treatment period (Baseline):
• Evaluation of eligibility through application of inclusion and exclusion criteria.
• Randomization.
• HIV test using a combined rapid test on saliva (4th generation), which detects antibodies against HIV produced by the individual and parts of the virus (such as the p24 antigen). This test, as reported on the Ministry of Health website (https://www.salute.gov.it/portale/hiv /dettaglioContenutiHIV.jsp?lingua=italiano&id=185&area=aids&menu=vuoto), can detect HIV infection as early as 20 days after exposure. The test result, available within minutes, was conducted at the medical office. If the result is doubtful or reactive (positive), the subject is not recruited.

• FOR WOMEN OF CHILD-BEARING AGE: At the initial visit, women of childbearing age underwent a pregnancy test using a test that measures levels of beta-HCG (human chorionic gonadotropin), which begins to be produced at the time of implantation in the uterine wall, approximately one week after fertilization. This test, which also provides results within a few minutes, was conducted at the medical office. If the result was doubtful or positive, the subject was not recruited.

• Outcomes assessment: IBS-SSS questionnaire, IBS-QoL and GIQLI questionnaires, Bristol Stool Form Scale, Bowel movement/week.
• Delivery of the bowel function diary.
• Delivery of the treatments.

T1. End of the treatment period (56 days from the start of the treatment period):
• Collection of the bowel function diary.
• Collection of treatment boxes (compliance assessment).
• Outcomes assessment: IBS-SSS questionnaire, IBS-QoL and GIQLI questionnaires, Bristol Stool Form Scale, Bowel movement/week.

Intervention Type
Supplement

Primary outcome(s)
The improvement of perceived gastrointestinal symptoms measured using the self-assessment questionnaire for gastrointestinal symptom severity characteristic of IBS IBS-Severity Scoring System (IBS-SSS) at baseline (t0) and day 56 (t1)

Key secondary outcome(s)
1. The improvement of individual quality of life measured using the validated questionnaire for self-assessment of quality of life in individuals with IBS, the IBS-Quality of Life (IBS-QoL) and the validated questionnaire for self-assessment of quality of life associated with gastrointestinal symptoms, the Gastrointestinal Quality of Life Index (GIQLI), at baseline (t0) and day 56 (t1)
2. The improvement of stool consistency measured using the validated tool that assesses stool consistency across a spectrum of seven types Bristol Stool Form Scale- BSFS at baseline (t0) and day 56 (t1)
3. The frequency of bowel movements measured using the number of bowel movements per week (Bowel Movements/Week- BM/WK), reported by the subject during visits (average of BM per week over the preceding 4 weeks) and recorded, throughout the study period in the Bowel Function Diary at baseline (t0) and day 56 (t1) and in the bowel function diary
4. The frequency and intensity of symptoms characteristic of IBS measured using a 5-point Likert scale (0 no discomfort – 5 maximum discomfort), included in the Daily Bowel Function Diary completed daily for the entire duration of the study
5. The reduction in the frequency of the use of salvage treatments measured using data that was recorded through the completion of the Bowel Function Diary daily for the entire duration of the study

Completion date
15/12/2024

Eligibility

Key inclusion criteria
1. Age ranging from 18 to 70 years
2. Capable of understanding and signing the informed consent
3. Negative HIV test
4. Negative pregnancy test
5. Symptoms of IBS for at least three months (onset at least six months prior), including recurrent abdominal pain occurring at least once a week, associated with two or more of the

following criteria: symptoms related to bowel movements and/or changes in the frequency of bowel movements and/or changes in stool consistency (Rome IV diagnostic criteria)
6. IBS forms considered were either with a predominance of constipation (stool consistency: more than 25% hard stools and less than 25% soft stools) or with a predominance of diarrhea (stool consistency: more than 25% soft stools and less than 25% hard stools)
7. Able to understand and adhere to the protocol requirements

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
70 Years

Sex
All

Total final enrolment
156

Key exclusion criteria
1. Age less than 18 or greater than 70 years
2. In a state of pregnancy or breastfeeding
3. Subjects with abdominal pain occurring less than once a week
4. Organic intestinal diseases
5. Gastrointestinal surgery
6. Parkinson's disease or Alzheimer's disease
7. Acquired immunodeficiency due to HIV
8. Opioid medications or other drugs that significantly impact intestinal function (e.g., antidepressants, aluminium-containing antacids)
9. Abuse alcohol, drugs, caffeine, or theine
10. Currently taking antibiotics or who have taken antibiotics in the past four weeks, or within the last six months, depending on the intensity and duration of the antibiotic treatment
11. Cognitive disorders that may hinder their ability to respond to questionnaires
12. Unwilling to collaborate
13. Difficulty attending the designated facility within the required times
14. Deemed ineligible by the principal investigator due to other conditions considered incompatible with enrollment
15. A known allergy to the ingredients in the experimental products (active or placebo)

Date of first enrolment
14/03/2024

Date of final enrolment
25/03/2024

Locations

Countries of recruitment
Italy

Study participating centre
COMEGEN General practitioner's medical center
Viale Maria Bakunin, 41
Naples
Italy
80126

Sponsor information

Organisation
Istituto Nazionale Biostrutture e Biosistemi

ROR
https://ror.org/043bhwh19

Funder(s)

Funder type
University/education

Funder Name
INBB Istituto Nazionale Biostrutture e Biosistemi - Consorzio Interuniversitario

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the subsequent results publication.

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		30/01/2026	21/01/2026	Yes	No