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The beneficial effect on intestinal function of two dietary supplements, one based on resistant dextrin from wheat starch, fibers from citrus (pectin), and fibers from oat, one based on resistant dextrin from wheat starch, fibers from carob, and fibers from oat.

Submission date 08/11/2024	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 19/11/2024	**Overall study status** Completed	
Last Edited 07/08/2025	**Condition category** Digestive System	

Plain English summary of protocol

Background and study aims
Constipation refers to difficulty in bowel movements, including infrequent bowel movements, hard stools, and excessive straining. Chronic constipation, lasting at least 3 months, affects 10-15% of people and can significantly impact quality of life. This study aims to test the effectiveness of two dietary supplements in improving bowel function in people with chronic constipation.

Who can participate?
Eighty-one adults aged 18-70 years with chronic constipation, who can understand and sign the informed consent, are eligible to participate.

What does the study involve?
Participants will be randomly assigned to one of three groups: two groups will receive different dietary supplements, and one group will receive a placebo. The study will last for one month, during which participants will take the assigned supplement or placebo and record their bowel movements and symptoms.

What are the possible benefits and risks of participating?
There are no expected risks from participating in this study. Participants may experience improved bowel function from the dietary supplements, but there is no guarantee of benefit.

Where is the study run from?
The study is conducted at COMEGEN, a general practitioner's medical center in Naples, Italy.

When is the study starting and how long is it expected to run for?
September 2023 to July 2025

Who is funding the study?
ESSERRE Pharma S.r.l. (Italy)

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
FIBERGUT23_01

Study information

Scientific Title
Efficacy study of two dietary supplements, one based on resistant dextrin from wheat starch, fibers from Citrus spp. (pectin), and fibers from oat (Avena sativa L.), one based on resistant dextrin from wheat starch, fibers from carob (Ceratonia siliqua L.), and fibers from oat (Avena sativa L.), on intestinal function in subjects with primary functional constipation: single-center, placebo-controlled, randomized clinical study, parallel arms, double-blind.

Acronym
FIBERGUT23

Study objectives
The study aimed to evaluate the efficacy of two dietary supplements. The first supplement contains resistant dextrin from wheat starch, fibers from Citrus spp. (pectin), and fibers from oats (Avena sativa L.), while the second contains resistant dextrin from wheat starch, fibers from carob (Ceratonia siliqua L.), and fibers from oats (Avena sativa L.). The goal is to evaluate their impact on improving intestinal function balance in subjects with chronic primary functional constipation, as defined by the Rome IV criteria.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 24/04/2024, Ethics Committee of CAMPANIA 1 (Via Mariano Semmola, 53, Naples, 80131, Italy; +39 081 17770131; comitatoetico@istitutotumori.na.it), ref: Prot n° 01/24

Study design

Interventional monocentric randomized parallel-group three-arm double-blind placebo-controlled clinical trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Chronic primary functional constipation

Interventions
The subjects recruited in the present clinical study have been randomized into the following experimental groups:
GROUP 1 - subjects who received the dietary supplement (TREATMENT A) containing resistant dextrin from wheat starch, fibers from Citrus spp. (pectins), and fibers from oats (Avena sativa L.)
GROUP 2 - subjects who received the dietary supplement (TREATMENT B) containing resistant dextrin from wheat starch, fibers from carob (Ceratonia siliqua L.), and fibers from oats (Avena sativa L.)
GROUP 3 - subjects who received the placebo.

The treatment period duration was 1 month.

To maintain the double-blind design, the three treatments will be unrecognizable, as the packaging is identical, and the dosage forms are 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 three 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).

In the clinical study, 81 participants will be enrolled and divided into three groups (27 for each group):
GROUP 1 (27 subjects) - subjects who received the dietary supplement (TREATMENT A) containing resistant dextrin from wheat starch, fibers from Citrus spp. (pectins), and fibers from oats (Avena sativa L.),
GROUP 2 (27 subjects) - subjects who received the dietary supplement (TREATMENT B) containing resistant dextrin from wheat starch, fibers from carob (Ceratonia siliqua L.), and fibers from oats (Avena sativa L.),
GROUP 3 (27 subjects) - subjects who received the placebo.

Participants underwent three visits (at the start of the run-in period of 28 days = tr, and at the end of the run-in period and the start of the treatment period (baseline) = t0, at the end of the treatment period of 28 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:

Tr . Run-in Phase :
• Evaluation of eligibility through the application of inclusion and exclusion criteria.
• Administration of the Informed Consent.
• Performance of an HIV test using a rapid combined saliva test (4th generation), which detects both anti-HIV antibodies and viral components (such as the p24 antigen). This test, as reported on the Ministry of Health's website (https://www.salute.gov.it/portale/hiv /dettaglioContenutiHIV.jsp?lingua=italiano&id=185&area=aids&menu=vuotocan detect an infection as early as 20 days. The test, which provides results in a few minutes, was conducted at the medical office. If the result was inconclusive or reactive (positive), the subject was not recruited.
• FOR WOMEN OF CHILDBEARING AGE: At the first visit, women of childbearing age underwent a pregnancy test measuring beta-HCG (human chorionic gonadotropin) levels, which begin to be produced upon implantation in the uterine wall, approximately one week after fertilization. This test, which provides results in a few minutes, was conducted at the medical office. If the result was inconclusive or positive, the subject was not recruited.
• Assessment of the subject's clinical status and medical history (including history of bowel dysfunction, diagnosis of primary chronic functional constipation, exclusion of organic causes, as well as BMI and waist circumference).
• Application of Inclusion and Exclusion Criteria.
• Random assignment to the three groups.
• Delivery of Bowel Function Diary.

T0. Start of the first treatment period (Baseline):
• Randomization.
• Delivery of Treatment or Placebo.
• Delivery of Bowel Function Diary.
• Primary Outcome Evaluation: Assessment of SCBM (patient-reported outcome over the past 4 weeks).
• Secondary Outcome Evaluations (patient-reported outcomes over the past 4 weeks):
• Bristol Stool Form Scale (BSFS)
• Symptoms
• Salvage treatment
• Quality of life questionnaire SF-12

T1. End of the treatment period (28 days from the start of the treatment period):
• Collection of Bowel Function Diary.
• Primary and Secondary Outcome Evaluations (patient-reported outcome over the past 4 weeks)
• Primary Outcome: SCBM (patient-reported outcome confirmation)
• Secondary Outcomes (patient-reported outcome confirmation):
o BSFS
o Symptoms
o Salvage treatment
o Quality of life questionnaire SF-12
• Collection of treatment (compliance assessment).
• Questions regarding any disorders or adverse events experienced

During the study, the following practices were applied. Subjects:
• Participants were not allowed to use medications as specified in the exclusion criteria. Subjects were required to promptly inform the physician of any medication or other remedies used, and the physician would assess whether to discontinue the subject's participation in the study ;
• Participants were not permitted to use dietary supplements;
• Participants were instructed not to alter their dietary habits from those followed before

enrollment in the study;
• Participants were required to complete the Bowel Function Diary daily and submit it to the investigators on scheduled visit days.

Intervention Type
Supplement

Primary outcome(s)
Measurement of the average number of spontaneous complete bowel movements (SCBM) per week in the preceding month as reported by the subject during and recorded in the Bowel Function Diary throughout the study period. The use of the diary is recommended by EMA guidelines as it helps avoid “recall bias” that may occur during visits.
SCBM per week in the preceding month: [Time frame: T0 (baseline), T1 (28 days of treatment)].
Bowel Function Diary: [Time frame: the diary was completed daily throughout the entire study duration (28-day run-in period and 28-day treatment period). The average values of spontaneous complete bowel movements (SCBM) per week recorded in the diary during the run-in period and the treatment period were compared in the statistical analysis.].

Key secondary outcome(s))
1. Stool consistency, which, in addition to the frequency of SCBM, is a valid indicator of functional constipation.
EVALUATION METHODS:
Bristol Stool Form Scale- BSFS , a validated tool that assesses stool consistency across a spectrum of seven types. Stool types 1 and 2 indicate hard or lumpy stools, while stool types 6 and 7 are indicative of soft or watery stools. Stools characteristic of individuals with constipation are types 1 or 2. Stool consistency was reported by the subjects during visits and recorded in the Bowel Function Diary throughout the study period.
[Time frame: T0 (baseline), T1 (28 days of treatment)].

2. Frequency of symptoms characteristic of constipated individuals (such as bloating and abdominal distension, feeling of heaviness, abdominal pain, and flatulence) which were reported by the subjects during visits and recorded in the Bowel Function Diary throughout the study period.
EVALUATION METHODS:
Bowel Function diary – BF diary. The diary consisted of:
o Sections that the subject was required to complete at the time of bowel movements (date and time, BSFS), and
o Sections that the subject was required to complete daily, regardless of the occurrence of an SCBM, including:
- Assessment of symptoms characteristic of constipation (bloating and abdominal distension, feeling of heaviness, abdominal pain, flatulence), using a 5-point Likert scale (0 no discomfort – 5 maximum discomfort),
- Use of any “salvage treatment”
- Daily recording of fluid intake
[Time frame: The diary was completed daily for the entire duration of the study].

3. Use of any “salvage treatment”.
EVALUATION METHODS:
Recording in the Bowel Function diary – BF diary. Subjects were required to record any use of "salvage treatment" (medications or other laxatives, including dietary supplements, enemas, or suppositories) in the diary to improve bowel function. The use of such treatments did not

directly lead to the exclusion of the subject from the study or the discontinuation of experimental treatments. However, whether to include or exclude the subject’s data in the results analysis was at the discretion of the principal investigator. Subjects were instructed by the investigators prior to the start of the treatment about the potential use of "salvage treatment." Specifically, rescue treatments were permitted if recorded in the diary and if the subject experienced a decrease of at least one SCBM per week.
[Time frame: The diary was completed daily for the entire duration of the study].

4. Assessment of the impact of constipation on perceived quality of life over the past 4 weeks.
EVALUATION METHODS:
Short Form Health Survey-12 (SF-12), a questionnaire developed from a multi-year study involving patients with chronic conditions. It is a validated tool widely used in clinical practice for self-assessment of quality of life concerning a general disorder.
[Time frame: T0 (baseline), T1 (28 days of treatment)].

Completion date
07/07/2025

Eligibility

Key inclusion criteria
1. Age ranging from 18 to 70 years
2. Able to understand and sign the informed consent
3. Negative HIV test
4. Negative pregnancy test
5. Able to understand and adhere to the protocol requirements
6. Experiencing symptoms of chronic constipation for at least 3 months (with onset at least 6 months prior)
7. Absent or non-dominant, occurring less than once a week, and thus not affected by IBS-C
8. Subjects had to have fewer than three SCBM per week and meet at least one of the following conditions:
8.1. Straining during more than 25% of bowel movements
8.2. Passage of lumpy or hard stools (BSFS type 1 or 2) in more than 25% of bowel movements
8.3. Sensation of incomplete evacuation in more than 25% of bowel movements
8.4. Sensation of anorectal obstruction/blockage in more than 25% of bowel movements
8.5. Use of manual maneuvers to facilitate bowel movements in more than 25% of bowel movements
9. Subjects who were not taking and would not take any type of medication throughout the study period

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
70 years

Sex
All

Total final enrolment
81

Key exclusion criteria
1. Age less than 18 or greater than 70 years
2. In a state of pregnancy or breastfeeding
3. Abdominal pain occurring at least once a week (subjects with IBS)
4. Subjects with organic intestinal diseases
5. Subjects with a history of gastrointestinal surgery
6. Subjects with gastroesophageal reflux
7. Subjects with Parkinson's disease or Alzheimer's disease
8. Subjects using opioid medications or other drugs with a significant impact on intestinal function (e.g., antidepressants, aluminum-containing antacids), subjects who are currently taking or have taken antibiotics within the past four weeks, or within the past six months depending on the intensity and duration of the antibiotic treatment, and subjects taking medications for other conditions
9. Subjects who abuse alcohol, drugs, caffeine, or theine
10. Subjects with cognitive impairments that may hinder their ability to respond to questionnaires
11. Subjects with a known allergy to the ingredients of the experimental products (active or placebo)
12. Subjects with acquired immunodeficiency syndrome (AIDS) due to HIV

Date of first enrolment
18/06/2024

Date of final enrolment
25/06/2024

Locations

Countries of recruitment
Italy

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

Sponsor information

Organisation
ESSERRE Pharma S.r.l.

Funder(s)

Funder type
Industry

Funder Name
ESSERRE Pharma S.r.l.

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes