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Effects of a dietary supplement (Eurekol™ based on BIOintestil®) on the intestinal symptoms of patients with irritable bowel syndrome

Submission date
09/12/2024

Recruitment status
No longer recruiting

Registration date
11/12/2024

Overall study status
Completed

Last Edited
10/12/2024

Condition category
Digestive System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Eurekol™ is a food supplement based on BIOintestil®, a mixture of Palmarosa (Cymbopogon martinii) essential oil, titrated in Geraniol, adsorbed on Ginger (Zingiber officinale) vegetable fiber, formulated as a support for the management of irritable bowel syndrome (IBS) symptoms. Eurekol™ has been produced in compliance with current regulatory provisions and duly notified to the Italian Ministry of Health. The BIOintestil® formulation is patented in Europe (EP3097921), and the safety of its components has been widely demonstrated through studies conducted in both laboratory animals and humans. The adsorption onto fiber makes Geraniol poorly absorbable in the small intestine. This allows the active ingredient to reach the colon, where it is released following the degradation of the fiber by resident microorganisms. Geraniol then acts topically, modulating the microbiota, often altered in patients with IBS, and restoring balance. Several studies have been conducted on this very low absorbable Geraniol formulation, demonstrating its efficacy. This trial aims to confirm the effect previously observed in patients with IBS.

Who can participate?
Patients diagnosed with IBS enrolled in private Italian gastroenterology practices

What does the study involve?
Private sites will handle enrolment, and the supplement will be administered to each patient for 30 days (2 tablets/day). The enrolment period will be 8 months, with a total study duration of 9 months. Each Investigator will provide two packages of Eurekol™ to cover the 30-day treatment. Eurekol™, containing BIOintestil® (a mixture of Palmarosa essential oil and Ginger fibre), will support IBS symptom management. Patients will complete the IBS-SSS questionnaire before and after treatment to assess symptoms and quality of life changes.

What are the possible benefits and risks of participating?
Patients will have the opportunity to try an innovative supplement specifically formulated for

the management of IBS symptoms, whose effectiveness has already been scientifically demonstrated. Additionally, they will be monitored by a gastroenterologist for the entire duration of the study. Therefore, no undesirable side effects were expected.

Where is the study run from?
Diadema Farmaceutici, Italy

When is the study starting and how long is it expected to run for?
February 2024 to November 2024

Who is funding the study?
Diadema Farmaceutici, Italy

Who is the main contact?
Giammario Piras (Project manager and study coordinator), g.piras@diademafarma.it

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Public

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Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
EK-01

Study information

Scientific Title
Very low-absorbable Geraniol in treatment of irritable bowel syndrome: a “real-life” open-label study on 1585 patients

Study objectives
The primary objective of the study was to confirm the effect of a very low absorbable Geraniol formulation (BIOintestil®) on self-reported symptoms of IBS and the quality of life of affected individuals, in a large sample of patients.
The secondary objectives were to confirm the effect of treatment with a very low absorbable Geraniol formulation on the different IBS subtypes.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 07/02/2024, Independent Ethical Committee for Non-Pharmacological Clinical Investigations - Italian Scientific Society (Via XX Settembre, 30/4, Genova, 16121, Italy; +39 0105454842; a.scudieri@studinonfarmacologici.it), ref: 2024/01

Study design
Interventional multicenter open-label clinical trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other therapist office

Study type(s)
Quality of life, Efficacy

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Irritable bowel syndrome

Interventions
This study is an interventional multicentre clinical trial, conducted open-label with the dietary supplement Eurekol™. Eurekol™ is a food supplement based on BIOintestil®, a mixture of Palmarosa (Cymbopogon martinii) essential oil, titrated in Geraniol, adsorbed on Ginger (Zingiber officinale) vegetable fibre, formulated as a support for the management of IBS symptoms.

The sites involved in enrolment are private practices and the food supplement will be administered to each patient in the study for 30 days (2 tablets/day). The enrolment period will be 8 months, and the total duration of the study will be 9 months. Each Investigator will assign two packages of Eurekol™ to each enrolled subject, which is sufficient to cover the recommended daily dose (2 tablets/day) for the 30 days of the planned treatment.

Every patient will be asked to complete the IBS-SSS (IBS-Severity Scoring System) questionnaire, before and after the treatment period, to assess any changes in symptoms and quality of life. Both the responses to the individual questions and the final scores will be compared. The percentage of responders will then be calculated: a reduction in IBS-SSS score ≥ 50 points is considered a clinically significant improvement.

Intervention Type
Supplement

Primary outcome measure
Changes in the severity of IBS symptoms in the total population measured using the IBS-SSS questionnaire before and after 30 days of treatment

Secondary outcome measures
1. Changes in the severity of IBS symptoms in IBS subtype populations (IBS-C; IBS-D; IBS-M and IBS-U) measured using the IBS-SSS questionnaire before and after 30 days of treatment
2. Changes in bowel function measured using the Bristol Stool Chart before and after 30 days of treatment

Overall study start date
07/02/2024

Completion date
15/11/2024

Eligibility

Key inclusion criteria
1. Age between 18 and 65 years
2. Signed informed consent
3. Diagnosis of IBS according to the Rome IV criteria
4. Body weight between 48 kg and 104 kg, with a BMI < 27

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
1800

Total final enrolment
1736

Key exclusion criteria
1. Known or suspected hypersensitivity to Palmarosa essential oil, Ginger or any excipients contained in the dietary supplement used for the treatment
2. Diagnosis of IBD, celiac disease or other severe systemic diseases
3. Severe concomitant diseases that, in the Investigator's opinion, contraindicate the patient's participation in the study
4. Lactose intolerance or confirmed food allergies
5. Use of steroidal anti-inflammatory drugs, antibiotics, or supplements and/or functional foods containing pre-/pro-biotics in the month preceding enrollment
6. Use of experimental drugs in the two months preceding enrollment

Date of first enrolment
15/02/2024

Date of final enrolment
10/10/2024

Locations

Countries of recruitment
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Funder(s)

Funder type
Industry

Funder Name
Diadema Farmaceutici

Results and Publications

Publication and dissemination plan
Planned publication in the journal Nutrients, an international, peer-reviewed, open-access journal of human nutrition published semimonthly online by MDPI.

Intention to publish date
20/12/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to ethical restrictions (patient confidentiality).

IPD sharing plan summary
Not expected to be made available