

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

<b>Submission date</b> 09/12/2024	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 11/12/2024	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 10/12/2024	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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

## Contact information

### Type(s)

Public

### Contact name

Mr Giammario Piras

### Contact details

Via Gaetano Malasoma, 14/16  
Pisa  
Italy  
56121  
+39 348.8255843  
g.piras@diademafarma.it

### Type(s)

Scientific, Principal Investigator

### Contact name

Prof Enzo Spisni

### ORCID ID

<https://orcid.org/0000-0002-8525-2981>

### Contact details

Via Selmi, 3  
Bologna  
Italy  
40126  
+39 0512094147  
enzo.spisni@unibo.it

## 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  $\geq 50$  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**

Italy

**Study participating centre**

**Marcello Acquaviva**

Via Wolfgang Amadeus Mozart, 61

Andria

Italy

76123

**Study participating centre**

**Barbara Bindi**

Viale Umberto I, 86

Sassari

Italy

07100

**Study participating centre**

**Carlo Casamassima**

Via San Cassano, 10

San Ferdinando di Puglia

Italy

76017

**Study participating centre**

**Monica Cesarini**

Via Alfredo Baccarini, 54

Roma

Italy

00179

**Study participating centre**

**Pietro Coccoli**

Via Sergio Pansini, 5

Napoli

Italy

80131

**Study participating centre**

**Danilo Consalvio**

Via Antonio Cardarelli, 9

Napoli

Italy

80131

**Study participating centre**

**Massimiliano De Seta**

Via Argine, 604

Napoli

Italy  
80147

**Study participating centre**  
**Simone Di Bella**  
Strada Statale 7 per Mesagne  
Brindisi  
Italy  
72100

**Study participating centre**  
**Maria Diaferia**  
Via Mariano Semmola, 52  
Napoli  
Italy  
80131

**Study participating centre**  
**Francesco Diterlizzi**  
Viale Ippocrate, 15  
Barletta  
Italy  
76121

**Study participating centre**  
**Vittorio D'Onofrio**  
Via Giovanni Pascoli, 23  
Pomigliano D'arco  
Italy  
80038

**Study participating centre**  
**Roberto Finizio**  
Via Fulda, 14  
Roma  
Italy  
00148

**Study participating centre**

**Giuseppe Fuggi**

Via Trento, 2  
Cacciano  
Italy  
82030

**Study participating centre****Pietro Fusaroli**

Via Montericco, 4  
Imola  
Italy  
40026

**Study participating centre****Stefano Grosso**

Via Bogliette, 3/c  
Pinerolo  
Italy  
038975

**Study participating centre****Maddalena Iadevaia**

Via Vincenzo Pirozzi, 20  
Pomigliano d'Arco  
Italy  
80038

**Study participating centre****Donato Iannunziello**

Via Sabin, 63  
Mola di Bari  
Italy  
70042

**Study participating centre****Nicola Antonio Lo Russo**

Via Wolfgang Amadeus Mozart, 61  
Andria  
Italy  
76123



**Study participating centre**

**Lucia Lorusso**

Via Comacchio, 239/A

Ferrara

Italy

44124

**Study participating centre**

**Marco Massidda**

SS 125 Orientale Sarda

Olbia

Italy

07026

**Study participating centre**

**Vincenzo Matarese**

Via Giovanni Verga, 17

Ferrara

Italy

44124

**Study participating centre**

**Francesca Murer**

Via Ca' Rotte, 9

Montecchio Maggiore

Italy

36075

**Study participating centre**

**Marco Niosi**

Piazza Luigi Miraglia, 5

Napoli

Italy

80138

**Study participating centre**

**Vittorio Maria Ormando**

Contrada Amoretta

Avellino

Italy  
83100

**Study participating centre**  
**Mauro Donato Pappagallo**  
Via Panunzio Giovanni, 33  
Molfetta  
Italy  
70056

**Study participating centre**  
**Davide Pardocchi**  
Via Giotto, 6  
Oristano  
Italy  
09170

**Study participating centre**  
**Giovanni Riccio**  
Corso Umberto I  
Mercato San Severino  
Italy  
84085

**Study participating centre**  
**Sara Rurgo**  
Via dei Mille, 40  
Napoli  
Italy  
80121

**Study participating centre**  
**Giuseppe Stoppino**  
Via Scaloria, 137  
Manfredonia  
Italy  
71043

**Study participating centre**

**Efisio Trincas**

Via Canalis, 9  
Oristano  
Italy  
09170

**Study participating centre****Giovanni Vicinanza**

Via Moro Aldo, 3  
Pompei  
Italy  
80045

## Sponsor information

**Organisation**

Diadema Farmaceutici

**Sponsor details**

Via Gaetano Malasoma, 14/16  
Pisa  
Italy  
56121  
+39 0509913750  
office@diademafarma.it

**Sponsor type**

Industry

**Website**

<https://www.diademafarma.it/it>

## 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