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Open-label, prospective, multicenter study to assess efficacy and safety of Lactacol, a food supplement in lactose intolerance

Submission date 26/09/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 16/10/2025	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 16/10/2025	**Condition category** Digestive System	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Lactose intolerance is a condition in which patients have digestive symptoms—such as bloating, diarrhea, and gas—after consuming food or drinks containing lactose. In lactose intolerance, digestive symptoms are caused by lactose malabsorption. Approximately 70% of the world's population has primary lactase deficiency. The percentage varies according to ethnicity and is related to the use of dairy products in the diet, resulting in genetic selection of individuals with the ability to digest lactose.
The study purpose is to assess the efficacy and safety of Lactacol, which is a food supplement designed to improve lactose digestion in individuals with lactose intolerance. It contains lactase enzyme and other components aimed at enhancing the breakdown of lactose and reducing gastrointestinal symptoms like bloating, diarrhea, and abdominal pain.

Who can participate?
1. Over 18 years.
2. Lactose Intolerance.
3. Signed Informed Consent for data collecting.

What does the study involve?
If the selection criteria are met the patient is enrolled into the study. The Product will be administered for 14 consecutive days before each meal that contains milk or dairy products.

There are visits as follows:
* Visit 1 – Screening and Enrollment visit – After signing the Informed Consent Form, the doctor evaluates the eligibility criteria, collects demographic data, checks the medical history, performs the physical examination, and assesses the concomitant diseases & medication; the clinical symptoms are also evaluated, and the product is allocated and administered.
* Visit 2 will take place 14 days (+/—1 days) after starting the product's administration. During this visit, the physical examination is performed, the clinical symptoms are revaluated, and product adherence is discussed Eventual adverse events and changes (if the case) in the concomitant medication are also discussed.

* Visit 3 (Phone Follow-up) will occur 21 days (+/- 2 days) after administering the Product. During this visit, the clinical symptoms are revaluated. Eventual adverse events and changes (if the case) in the concomitant medication are also discussed.

What are the possible benefits and risks of participating?
This Product could be beneficial for you in relieving the symptoms you are experiencing such as bloating, abdominal pain, diarrhoea, flatulence, nausea, discomfort, increasing the quality of life. The research product may or may not give you personal benefits. Even if there are no benefits for yourself, this research's results may help improve the product's efficiency and safety profile. The participation in this research is voluntary.
If this plan does not deliver the expected results, the doctor decides if to continue administering the product. Lactacol is a dietary supplement based on lactase, which helps with lactose digestion by reducing fermentation and gas production. There are no side effects known in Lactacol administration.

Where is the study run from?
1. Ambulatory practice for individual primary outpatient medical care Magsmed EOOD, Sofia (Bulgaria)
2. Ambulatory Practice for Primary Outpatient Medical Care SANA OOD, Sofia (Bulgaria)
3. Ambulatory practice for individual primary outpatient medical care d-r Teodora Marinova EOOD, Sofia (Bulgaria)

When is the study starting and how long is it expected to run for?
August 2024 to September 2025

Who is funding the study?
Pharmunion LLC (USA)

Who is the main contact?
Mrs Alina Iordache, alina.iordache@cebis-int.com

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
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Additional identifiers

Protocol serial number

CBSPH18102024

Study information

Scientific Title
Open-label, prospective, multicenter study to assess efficacy and safety of Lactacol, a food supplement in lactose intolerance

Acronym
CARE study

Study objectives
To assess the efficacy and safety of Lactacol.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 12/02/2025, Local ethics committee at Ambulatory Practice for Primary Outpatient Medical Care SANA OOD (8 Academic Stefan Mladenov Street, Sofia, 1700, Bulgaria; +35 9878315977; bkdoganov@gmail.com), ref: 3

Primary study design
Observational

Study design
Open-label multicenter prospective non-comparative non-interventional study

Study type(s)
Safety, Efficacy

Health condition(s) or problem(s) studied
Lactose intolerance

Interventions
This non-interventional study is conducted in Bulgaria in routine clinical practice by GPs . Data will be collected prospectively. Lactacol will be administered in accordance with approved leaflet. Patient demographic data would be collected during screening visit where available (e.g., age, gender, geographic location). All the assessments for primary and secondary objectives will be performed at baseline and periodically according to national standards, routine clinical practice, and this study protocol.

Intervention Type
Supplement

Primary outcome(s)
Bloating measured daily from Day 0 to Day 14 and at Day 21 using a 5-point frequency score (Never = 0, Rarely = 1, Sometimes = 2, Often = 3, Always = 4).

Key secondary outcome(s)

1. Abdominal pain measured using a 5-point frequency score (Never = 0, Rarely = 1, Sometimes = 2, Often = 3, Always = 4) and a 5-point severity score (No symptoms = 0, Mild = 1, Moderate = 2, Severe = 3, Very severe = 4) at Day 0, Day 14 and Day 21.
2. Diarrhoea measured using a 5-point frequency score (Never = 0, Rarely = 1, Sometimes = 2, Often = 3, Always = 4) and a 5-point severity score at Day 0, Day 14 and Day 21.
3. Flatulence measured using a 5-point frequency score (Never = 0, Rarely = 1, Sometimes = 2, Often = 3, Always = 4) and a 5-point severity score at Day 0, Day 14 and Day 21.
4. Nausea measured using a 5-point frequency score (Never = 0, Rarely = 1, Sometimes = 2, Often = 3, Always = 4) and 5-point severity score at Day 0, Day 14 and Day 21.
5. Discomfort measured using a 5-point frequency score (Never = 0, Rarely = 1, Sometimes = 2, Often = 3, Always = 4) and 5-point severity score at Day 0, Day 14 and Day 21.
6. Quality of Life (QoL) measured using the Visual Analogue Scale (VAS) at Day 0 and Day 14.
7. Investigator's Final Evaluation assessed at Day 21.
8. Adverse events recorded during the study period (Day 0 to Day 21).
9. Participant withdrawals due to lack of tolerability recorded during the study period (Day 0 to Day 21).

Completion date
02/09/2025

Eligibility

Key inclusion criteria
1. Adult participants over 18 years old
2. Established diagnosis: Lactose Intolerance, with:
2.1. In terms of frequency, there should be at least one baseline symptom occurring "often" or "always," and no symptom notated with "0" ("never")
2.2. In terms of severity, there should be at least one baseline symptom with a severity score of 2 (Moderate) or higher and no symptom notated with "0" ("no symptoms")
3. Signed Informed Consent for data collecting

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
79 Years

Sex
All

Total final enrolment

30

Key exclusion criteria
1. Unwillingness to provide signed Informed Consent for data collecting
2. Patients participating in other trials
3. Allergy to any of the product ingredients

Date of first enrolment
01/04/2025

Date of final enrolment
30/05/2025

Locations

Countries of recruitment
Bulgaria

Study participating centre
Ambulatory practice for individual primary outpatient medical care Magsmed EOOD
8 Academic Stefan Mladenov Street,
fl. 1, office 12
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1700

Study participating centre
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Sponsor information

Organisation
Pharmunion LLC

Funder(s)

Funder type
Industry

Funder Name
Pharmunion LLC

Results and Publications

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 the confidential nature of the data.

IPD sharing plan summary
Not expected to be made available