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

**Submission date**
26/09/2025

**Recruitment status**
No longer recruiting

**Registration date**
16/10/2025

**Overall study status**
Completed

**Last Edited**
16/10/2025

**Condition category**
Digestive System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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. Approximately 20% of Hispanic, Asian, and black children younger than 5 years of age have evidence of lactase deficiency and lactose malabsorption, whereas white children typically do not develop symptoms of lactose intolerance until after 4 or 5 years of age. 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. Pediatric population : 7 months – 7 years.
2. Established diagnosis: Lactose Intolerance.
3. Signed Informed Consent for data collecting.

What does the study involve?
If the selection criteria are met, the child is enrolled in the research. The Product is to 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 child's doctor evaluates the eligibility criteria, collects demographic data, checks the child's medical history, performs the child's physical examination, assesses the concomitant diseases & medication; the doctor also evaluates the clinical symptoms the child is experiencing and the product is allocated and administered.
* Visit 2 will take place 14 days (+/—1 days) after starting the administration of the Product. During this visit, the child's 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 take place 21 days (+/- 2 days) after the administering of 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.
2. Ambulatory Practice for Primary Outpatient Medical Care SANA OOD, Sofia.
3. Ambulatory practice for individual primary outpatient medical care d-r Teodora Marinova EOOD, Sofia.

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
Mrs Alina Iordache

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# Additional identifiers

### Protocol serial number
CBSPH12092024

# Study information

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

### Acronym
PACE 2 Study

### Study objectives
To assess the efficacy and safety of Lactacol in children.

### 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: 2

### 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 in children

### Interventions
This non-interventional study is conducted in Bulgaria in routine clinical practice by GPs or Pediatricians. 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. Pediatric population : 7 months – 7 years.
2. Established diagnosis: Lactose Intolerance with: in terms of frequency, there should be at least one baseline symptom occurring "often" or "always," and no symptom notated with "0" ("never")
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
Child

### Lower age limit
7 Months

### Upper age limit
7 Years

### Sex
All

### Total final enrolment
30

### Key exclusion criteria
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
02/04/2025

### Date of final enrolment
02/06/2025

## 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
Sofia
Bulgaria
1700

### Study participating centre
**Ambulatory Practice for Primary Outpatient Medical Care SANA OOD**
8 Academic Stefan Mladenov Street
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### Study participating centre
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7 Doktor Stefan Sarafov Street, fl. 1, office 18
Sofia
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1408

## 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