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Open-label, prospective, multicenter study to assess efficacy and safety of Lactacol /Lactazak®, a food supplement in intestinal colic and bloating

Submission date
14/08/2024

Recruitment status
No longer recruiting

Registration date
26/08/2024

Overall study status
Completed

Last Edited
08/08/2025

Condition category
Digestive System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Infant colic is a condition in which a healthy baby, typically between the ages of a few weeks and three to four months, experiences episodes of excessive, unexplained crying or fussiness. Infant colic is challenging for new parents and is a reason for 10% to 20% of pediatrician visits during the early weeks of an infant's life. Colic is estimated to affect 5% to 40% of infants worldwide. The condition typically presents in the second or third week of life, peaks around 6 weeks, and resolves by the age of 12 weeks in 60% of infants and by 16 weeks of age in 90%. Inconsolable crying, irritability, and screaming without an obvious cause characterize colic; during these episodes of fussiness, which occur more frequently in the evenings, the affected infant classically appears red-faced, draws up the legs, and tenses up the abdomen.
Studies have shown that up to 40% of babies medically diagnosed with colic actually suffer from transient lactase intolerance, hence the common term “colic associated with lactose intolerance”. Many of these babies can be helped by pre-treating baby feeds with lactase enzymes. Lactacol/Lactazak® can be used as a dietary supplement to a healthy diet and as a source of lactase enzymes.

Who can participate?
• Pediatric population 0-4 months;
• Established diagnosis: FGIDs (intestinal colic and bloating).
• Signed Informed Consent for data collecting

What does the study involve?
This research aims to assess the product efficiency and safety of Lactacol/Lactazak ® - in the pediatric population 0-4 months – in reducing the baby crying due to colic during the study period and reducing bloating.
If the parent signs the Informed Consent Form and the selection criteria are met, the child will be enrolled in the research. According to the approved leaflet, the product is to be administered for 14 consecutive days.

There are three visits as follows:
• Visit 1 – Screening and Enrollment visit – demographic data will be collected, the child's medical history will be checked, the child's physical examination will be performed, the concomitant diseases & medication will be assessed; the doctor will also evaluate the clinical symptoms the child is experiencing and the product will be allocated.
• Visit 2 will take place 14 days (+/—2 days) after starting the administration of the Product. During this visit, the child's physical examination will be performed, the clinical symptoms will be reevaluated, and product adherence and eventual adverse events will be discussed.
• Visit 3 (Phone Follow-up) will take place 28 days (+/—5 days) after the Product is administered. During this visit, the clinical symptoms will be reevaluated, and any potential adverse events will be discussed.
During this research, the child will not take other similar products.

What are the possible benefits and risks of participating?
This Product could benefit the child by relieving his symptoms: the baby crying due to colic and bloating.
The research Product may give him personal benefits or not. Even if there are no benefits for him, 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 child's doctor will decide whether or not to continue administering this product.

Lactacol/Lactazak ® is a dietary supplement based on Lactase, which helps lactose digestion by reducing fermentation and gas production. There are no side effects known in Lactacol/Lactazak ® administration. You, as the child's legal representative, are not obliged to participate in this research, and the doctor will tell you about other solutions and their risks and benefits. The child's physician will recommend the treatment strategy for him. So, the doctor may prescribe an alternative Product.

Where is the study run from?
Ambulatory Practice for Primary Outpatient Medical Care SANA OOD (Bulgaria)

When is the study starting and how long is it expected to run for?
December 2022 to June 2024

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

Contact details

47 Theodor Pallady
Helios Business Centre, Entrance B, 3rd Floor
Bucharest
Romania
032275
+40 (0)737640721
alina.iordache@cebis-int.com

Additional identifiers

Protocol serial number
CBSPH_CBS12122022

Study information

Scientific Title
Open-label, Prospective, multicenter study to Assess effiCacy and safEty of Lactacol/Lactazak®, a food supplement in intestinal colic and bloating

Acronym
PACE

Study objectives
Studies have shown that up to 40% of babies medically diagnosed with colic actually suffer from transient lactase intolerance, hence the common term "colic associated with lactose intolerance". Pre-treating babies' feeds with lactase enzymes can help many of these babies. The study sponsor introduces Lactacol/Lactazak®, which can be used as a dietary supplement for a healthy diet and as a source of lactase enzymes.
Lactacol/Lactazak ® characteristics are:
• Contains highly active lactase enzymes of plant origin.
• Resistant to acidic gastric medium.
• Maintains its activity in conditions of high pH variations.
Lactacol/Lactazak promotes lactose hydrolysis and should be used during each feeding during the first 3-4 months of life.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 10/01/2024, Local Ethics Committee at Ambulatory Practice for Primary Outpatient Medical Care "Sana" Ood (8 Academic Stefan Mladenov Street, Sofia, 1700, Bulgaria; +359878315977; bkdoganov@gmail.com), ref: 1

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
Intestinal colic and bloating

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

Intervention Type
Supplement

Primary outcome(s)
1. Baby's crying due to colic (number of babies crying episodes during 24 h) measured by reviewing patient’s diary daily
2. Bloating measured using (3-point Likert scale: 1 – None, 2 – Moderate, 3 – Intense) recorded in patient’s diary daily

Key secondary outcome(s)
To assess the effectiveness of the product administration by the responses to below questions during the study period:
1. “How many hours in total does your child sleep per 24-h period?”
2. “How many hours in total do you (as caregiver) sleep per 24-h period?”
3. “How often does your child usually wake during the night?”

To assess the safety of the product administration in terms of the following:
1. AE occurrence when reported by the caregiver
2. Withdrawals due to lack of tolerability when reported by the caregiver

Completion date
13/06/2024

Eligibility

Key inclusion criteria
1. Pediatric population 0-4 months
2. Established diagnosis: FGIDs (intestinal colic and bloating)
3. Signed Informed Consent for data collecting

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
0 Months

Upper age limit
4 Months

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
23/01/2024

Date of final enrolment
16/05/2024

Locations

Countries of recruitment
Bulgaria

Study participating centre
Ambulatory Practice for Primary Outpatient Medical Care SANA OOD
8 Academic Stefan Mladenov Street
Sofia
Bulgaria
1700

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Funder report results	version 1.0	01/07/2024	06/08/2025	No	No
Participant information sheet	version 1.0	27/11/2023	06/08/2025	No	Yes
Protocol file	version 1.0	27/11/2023	06/08/2025	No	No