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Evaluation of Lactosectan versus placebo to compare the effectiveness and safety in treating adult patients with intolerance to certain foods, primarily lactose intolerance

Submission date
25/11/2021

Recruitment status
No longer recruiting

Registration date
16/12/2021

Overall study status
Completed

Last Edited
06/01/2023

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Food intolerance and lactose intolerance have common symptoms. Food intolerance, also known as non-IgE mediated food hypersensitivity or non-allergic food hypersensitivity, refers to a difficulty in digesting certain foods. In food intolerance, people can tolerate different amounts of the food, but when they eat too much (or too often) they get symptoms because their body cannot tolerate unlimited amounts. Symptoms such as fatigue, joint pains, dark circles under the eyes, night sweats, gastrointestinal symptoms such as diarrhoea and vomiting, bloating, irritable bowel, skin symptoms such as rashes, eczema are most common symptoms of food intolerance.
Lactose intolerance is the inability or the insufficient ability to digest lactose. It develops naturally as people grow older as the small intestine produces less lactase (which breaks down lactose). Certain digestive diseases such as irritable bowel syndrome, Crohn's disease, celiac disease (a digestive disease that damages the small intestine and interferes with absorption of nutrients from food), infections, and injuries to the small intestine can also reduce the amount of lactase available to process lactose properly.
It is not easy to initially determine whether an individual has a food intolerance or allergy because the signs and symptoms often overlap between food intolerance, lactose intolerance and food allergy.
Apart from lactose intolerance there is no accurate, reliable and validated test to identify food intolerance and usually the treatment consists of exclusion diets (removing certain foods from the diet). Lactose intolerance is also responsible for food intolerance. Maintaining tolerance is often a question of knowing how long to abstain, and how much of it to eat when it is being reintroduced
A diagnosis of food intolerance may be difficult and based on dietary exclusion. A number of methods are available but the lactose breath hydrogen test is considered a very simple, useful and most reliable test in subjects with suspected lactose intolerance. Recently a new genetic test has been proposed, complementing the role of breath testing.
Novintethical Pharma SA has developed a new formulation for treating the symptoms of lactose intolerance and intolerance called Lactosectan. It is intended for the reduction of the symptoms

secondary to lactose maldigestion, reducing the discomfort related to lactose intake, such as bloating, flatulence, and abdominal pain. It is also thought to protect the intestinal lining.
The aim of this study is to assess the effectiveness of Lactosectan at reducing the symptoms of lactose intolerance in adult patients.

Who can participate?
Patients aged 18 to 64 years with a current or recently reported history of lactose intolerance of at least 1-month duration.

What does the study involve?
Participants are randomly allocated to take Lactosectan or a placebo orally three times per day for 7 days, then they swap and take the other treatment for 7 days. They will keep a journal with the type and quantities of the dairy products they consume over the treatment period. They will be advised not to consume more than 500 ml of dairy products per day.

What are the possible benefits and risks of participating?
This treatment could be very helpful for treating and relieving the symptoms of lactose intolerance or the inability to digest lactose. If no results are obtained according to the treatment plan, a gastroenterologist will decide whether or not to continue the treatment.
There are no expected risks.

Where is the study run from?
Novintethical Pharma SA (Switzerland)

When is the study starting and how long is it expected to run for?
April 2015 to January 2018

Who is funding the study?
Novintethical Pharma SA (Switzerland)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2014-005405-20

Protocol serial number
CEBLCT041214

Study information

Scientific Title
A double blind-cross-over, parallel, randomized, multicenter study to evaluate the safety and efficacy of LTS035 (Lactosectan) vs placebo in adult subjects with intolerance to certain foods, primarily lactose intolerant

Acronym
EFFECT

Study objectives
This is a Phase IV, double-blind, cross-over, randomized, and parallel multicenter study to evaluate the safety and efficacy of LTS035 (Lactosectan) vs. placebo in adult patients with intolerance to certain foods, primarily lactose intolerant.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/11/2016, National Commission for Bioethics of Medicines and Medical Devices (Comisia Nationala de Bioetica a medicamentului si a Dispozitivelor Medicale, Stefan Cel Mare 19-21 Road, District 2, Bucharest, Romania; +40 (0)212102880; comisia.bioetica@adsm.ro), ref: 8DM /28.09.2016

Primary study design
Interventional

Study design
Open-label randomized multi-center study

Study type(s)
Treatment

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

Interventions

Subjects meeting all eligibility criteria will be randomized using a 1:1 ratio (Lactosectan: placebo) based on the randomization sequence and documented in the study file.

Group A will receive treatment A for 7 days, and group B will receive treatment B for 7 days. After 7 days the groups cross over: group A will receive treatment B for the other 7 days, and group B will receive product A for another 7 days.

The treatments (Product A or Product B) will be administered by the oral route. During the 14-day treatment period, all subjects will be asked to keep a daily journal of the type and quantities of the dairy products they consume. All subjects will be advised not to consume more than 500 ml of dairy products per day.

Visit 1 - Patients will sign the informed consent form and they will undergo hydrogen breath tests (HBT)
Visit 2 - HBT test, randomization, treatment allocation, Group A will receive product A, Group B will receive product B
Visit 3 - HBT test to test the speed of action
Visit 4 - Group A will finish the treatment with product A according to the leaflet and Group B will finish treatment with product B, and crossover to the second line of treatment (Group A will receive product B and Group B will receive product A)
Visit 5 - HBT test to test the speed of action
Visit 6 - HBT final test

Intervention Type
Device

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Lactosectan

Primary outcome(s)
Efficacy evaluated in terms of:
1. Tolerability of food intake assessed using a daily journal kept for the entire period of the study treatment
2. Symptom reduction (bloating, distension, pain) assessed by the Likert scale using a daily journal kept for the entire period of the study treatment
3. Speed of action assessed using the hydrogen breath test (HBT) on V2 (day 1 of treatment), V3 (day 2 of treatment), V4 (end of first-line treatment and crossover) to V5 (after cross-over the first day of the second-line treatment)

Key secondary outcome(s)
The safety of the LTS035 study formulation evaluated by monitoring the occurrence of undesirable effects reported by the patient or observed by the physician during the whole study period

Completion date
12/01/2018

Eligibility

Key inclusion criteria
1. Aged 18 to 64 years with a current or recently reported history of dairy intolerance of at least 1-month duration
2. Caucasian race
3. Willing to sign the informed consent form

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
60

Key exclusion criteria
1. Pregnant or breastfeeding women
2. Unwilling to sign the informed consent form
3. Allergy to one of the product ingredients
4. Cannot to come to the study visits
5. Patients with celiac disease
6. Patients with gastroenteritis
7. Patients with Crohn’s disease
8. Using lactase enzyme tablets or drops
9. Used antibiotics in the last 4 weeks
10. Used laxatives in the last 2 weeks
11. Laxatives used for a colonoscopy within the last 2 weeks
12. Diabetic patients

Date of first enrolment
09/02/2017

Date of final enrolment
29/12/2017

Locations

Countries of recruitment
Romania

Study participating centre
Clinical Emergency University Hospital
Splaiul Independenței 169
Bucharest
Romania
050098

Study participating centre
Clinical Emergency University Hospital
Bulevardul Liviu Rebreanu 156
Timisoara
Romania
300723

Study participating centre
Clinical Emergency University Hospital- Elias
Bulevardul Mărăști 17
Bucharest
Romania
011461

Study participating centre
Clinical Emergency Hospital,
Calea Floreasca 8
Bucharest
Romania
014461

Sponsor information

Organisation
Novintethical Pharma SA

Funder(s)

Funder type
Industry

Funder Name
Novintethical Pharma SA

Results and Publications

Individual participant data (IPD) sharing plan
The data will be collected under the study confidentiality and for study purposes only, according to the approved informed consent form. The study data will be archived according to the sponsor requirements and local regulatory requirements.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		26/08/2022	06/01/2023	Yes	No