ISRCTN61965252 https://doi.org/10.1186/ISRCTN61965252

Trial to evaluate the efficacy and safety of a combination of xyloglucan and gelose associated to oral rehydration salts for the treatment of acute diarrhea in children

Submission date
15/04/2020

Recruitment status
No longer recruiting

Registration date
24/04/2020

Overall study status
Completed

Last Edited
12/05/2021

Condition category
Digestive System

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

Plain English summary of protocol

Background and study aims
Acute diarrhea, with or without vomiting, is a frequent problem in childhood. It is the second leading cause of death (after pneumonia), especially in children aged <3 years, and mortality is most frequent in low-income regions. Acute diarrhea is associated to high incidence of dehydration in infants. Other direct consequences of diarrhea in children include growth faltering, malnutrition, and impaired cognitive development in resource-limited countries. Oral rehydration and usage of oral rehydration salts (ORS) is the first-line treatment for all the children with acute diarrhea.
A new class of products, defined as “mucosal protectors” has been developed for use in gastroenteric diseases. These products form a bioprotective film on the intestinal mucosa, improving the resistance of the mucosa to pathologic aggression and helping to restore normal function. Among these film-forming products, Xyloglucan (extracted from the seeds of the tamarind tree) is currently being studied and used for gastroenteric disorders.
This is a clinical trial to evaluate efficacy and safety of a combination of Xyloglucan and Gelose associated to Oral Rehydration Salts (ORS) for treatment of acute diarrhea in children.
The product works by forming a film which protects the intestinal mucosa, reducing the frequency and duration of diarrhoea episodes.
The primary objective of the study is to assess the efficacy of the product and the secondary objective is to assess safety.

Who can participate?
Children aged between three months and 14 years, suffering from acute gastroenteritis.

What does the study involve?
The study will include 120 subjects split into two groups: 60 subjects will receive the active product (xyloglucan and gelose+ORS) and the other 60 subjects will receive a product with no active ingredients (Placebo) + ORS. Neither subjects nor doctors will not know who receives the active product or the Placebo in order to avoid bias. The products will be administered to the

subjects who meet the eligibility criteria and gave their informed consent to participate in the study. The treatments will be administrated by oral route. The treatment duration will be 5 days, and the total period of the study will be 7 days (including a follow-up visit at day 7).

What are the possible benefits and risks of participating?
The tested product could help reduce the symptoms of acute diarrhea and duration of diarrhea (by normalization of stool number and consistency). The risk of participating in the study is considered minimal to none as the procedures pose no harm to the subjects. The tested product is a medical device which has as main ingredients xyloglucan and gelose for which there are no known risks associated with their administration.

Where is the study run from?
CEBIS International (Romania)

When is the study starting and how long is it expected to run for?
August 2019 to November 2019

Who is funding the study?
NOVENTURE S.L. (Spain)

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

Contact information

Type(s)
Scientific

Contact name
Mrs Alina Maria Lordache

ORCID ID
https://orcid.org/0000-0002-5931-0463

Contact details
CEBIS Int.
Theodor Pallady Boulevard, 47
Helios Business Center Buliding, B entrance, Third floor
District 3
Bucharest
Romania
032258
+40 737640721
alina.iordache@cebis-int.com

Additional identifiers

Protocol serial number
IDCEB04-10

Study information

Scientific Title
A randomized, double-blind, controlled trial to evaluate the efficacy and safety of a combination of xyloglucan and gelose associated to oral rehydration salts for the treatment of acute diarrhea in children (iDEA STUDY)

Acronym
iDEA STUDY

Study objectives
A combination of Xyloglucan + gelose (Agar-agar) could help in the treatment of acute diarrhea in children in terms of reduction of the symptoms by restoring the physiological functions of the intestinal wall. This combination acts by forming a film which protects the intestinal mucosa, reducing the frequency and duration of diarrhoea episodes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/07/2019, National Committee for Bioethics of Medicinal Products and Medical Devices (19-21 Stefan Cel Mare Street, District 2, Bucharest, Romania, 020125; +40 212102880; comisie@bioetica-medicala.ro), ref: 1DM/02.07.2019

Primary study design
Interventional

Study design
Interventional double blind placebo controlled multicentre randomized clinical trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Acute diarrhea

Interventions
The investigators will enroll in this study 120 subjects accordingly to the inclusion and exclusion criteria. The patient will be assigned to the experimental group(A) or control group(B) by using a computer-generated randomization sequence using a 1:1 ratio. Group A will receive Xyloglucan + gelose (Agar-agar) + Oral Rehydration Salts and Group B will receive Placebo + Oral Rehydration Salts. The products will be administered by oral route: children <3 years old: one sachet every 8 hours for 5 consecutive days, and children >3 years old: two sachets every 8 hours for 5 consecutive days

Intervention Type
Device

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Xyloglucan + gelose (Agar-agar)

Primary outcome(s)
Duration of diarrhea, defined as the time until the normalization of stool consistency according to the Bristol stool form(BSF) scale (in BSF scale, numbers 2, 3, 4 and 5) or the time until the normalization of the number of stools (compared with the period before the onset of diarrhea) and the presence of normal stools for 48 h. Stool number and type evaluation will be done in each of the 5 days using the BSF scale.

Key secondary outcome(s)
1. Symptoms evaluation: vomiting, no. of stools, type of stools, flatulence, presence of blood in stool, apathy) and monitoring of adverse events and concomitant medication measured by the experimenter on each of the 5 days and at day 7
2. Morphological parameters (height, weight, abdominal girth) and Hemodynamic parameters (blood pressure [SBP, DBP]; pulse, temperature; respiration) measured at day 1, 5 and 7
3. Laboratory Investigations (urine summary, CBC, C-reactive protein, transaminases, glucose, coprocitogram) measured at day 1 and 5

Completion date
29/11/2019

Eligibility

Key inclusion criteria
1. Acute gastroenteritis defined as a change in stool consistency according to the Bristol Stool Form (BSF) scale and/or an increase in the frequency of evacuations (typically ≥3 in 24 h) lasting more than 1 day and no longer than 3 days
2. Age group of children between ≥ 3 months and ≤ 14 years
3. A caregiver must provide written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
3 Months

Upper age limit
14 Years

Sex
All

Total final enrolment

100

Key exclusion criteria
1. Use of antibiotics, gelatine tannate, diosmectite, other probiotics, racecadotril, or zinc (including zinc containing ORS) within a week prior to enrolment
2. Exclusive breast feeding
3. Chronic diarrheal gastrointestinal disease (eg. inflammatory bowel diseases, cystic fibrosis, coeliac disease, food allergy)
4. Immunodeficiencies
5. Malnutrition (weight/height/length under 3rd percentile) (WHO Child Growth Standards will be used)
6. If needed, discontinuation or modification of the treatment may be considered at the discretion of the physician

Date of first enrolment
08/08/2019

Date of final enrolment
22/11/2019

Locations

Countries of recruitment
Romania

Study participating centre
“Victor Babeş" Clinical Hospital
Mihai Bravu Street, 281
Bucharest
Romania
030303

Study participating centre
“Sf. Parascheva” Infectious Diseases Hospital
Octav Botez Street, 2
Iasi
Romania
700116

Study participating centre
"Louis Ţurcanu” Clinical Emergency Hospital
Doctor Iosif Nemoianu Street, 2
Timisoara
Romania
300011

Study participating centre
Clinical Hospital of Infectious Diseases of Constanta
Ferdinand Boulevard, 100
Constanta
Romania
900178

Study participating centre
"Dr. Victor Babes" Clinical Hospital of Infectious Diseases and Pneumophtisiology
Gheorghe Adam Street, 13
Timisoara
Romania
300310

Study participating centre
“Prof. Matei Balş” National Institute of Infectious Diseases
Dr. Calistrat Grozovici Street. 1
Bucharest
Romania
021105

Sponsor information

Organisation
NOVENTURE S.L.

Funder(s)

Funder type
Industry

Funder Name
NOVENTURE S.L.

Results and Publications

Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/03/2021	12/05/2021	Yes	No