Film forming devices in the treatment of children with acute gastroenteritis receiving oral rehydration solution (ORS): the Tasectan Plus in Children Study

Submission date	Recruitment status No longer recruiting	Prospectively registered		
24/06/2015		☐ Protocol		
Registration date 28/08/2015	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited 24/05/2016	Condition category Digestive System	[] Individual participant data		
24/03/2010	Didestive System			

Plain English summary of protocol

Background and study aims

The aim of this study is to investigate whether Tasectan Plus is better than treating acute diarrhoea in children with acute gastroenteritis receiving oral rehydration solution (ORS) than when they are treated with ORS alone.

Who can participate?

Children between 3 months to 12 years with acute diarrhoea.

What does the study involve?

Participants are randomly assigned into one of two groups. Those in group 1 are given Tasectan Plus with oral rehydration salts for 5 days. Those in group 2 are given only the oral rehydration salts. The treatment used in the study was according to products's leaflet. The parents/tutors are asked to present at doctor's office 2 days later (or earlier if necessary as a result of the worsening of symptoms). During this visit the physician reviews the diary regarding the symptoms and any reported side effects. Further follow-up visits occur 5 days after the start of treatment and then again after 10 days.

What are the possible benefits and risks of participating?

Treatment offered in this study has the potential to treat a childs acute diarrhoea. Information obtained from this study may also help the researchers to better treat children aged 3 months - 12 years with acute diarrhoea. The treatments are given to the children according to the approved leaflet of each product. If the child required medical treatment for physical injury or disease directly caused by the use of the medical device in this study they will be reimbursed the necessary expenses for medical treatment.

Where is the study run from? A total of seven private GPs in Romania. When is the study starting and how long is it expected to run for? July 2014 to February 2015

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

Who is the main contact? Mr Manolache Mihal mihai.manolache@cebis-int.com

Contact information

Type(s)

Public

Contact name

Mr Manolache Mihai

ORCID ID

https://orcid.org/0000-0002-1811-3965

Contact details

CEBIS International
222 Plevnei Street, 3rd Floor
Bucharest
Romania
060016
+40731834503
mihai.manolache@cebis-int.com

Additional identifiers

Clinical Trials Information System (CTIS) 2014-001814-24

Protocol serial number CNTPK0414

Study information

Scientific Title

A multicentre, randomized, open label, two parallel groups (ORS versus ORS + Tasectan Plus) of children aged 3 months to 12 years with acute gastroenteritis (acute infectious diarrhoea).

Study objectives

Is Tasectan Plus better in reducing the duration of acute infectious diarrhoea in children aged 3 months to 12 years with acute gastroenteritis receiving oral rehydration solution (ORS)?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethical Committee of Scientific Research, Targu Mures, Romania, 08/07/2014

Study design

Multicentre randomized open-label parallel controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Acute gastroenteritis (acute infectious diarrhoea)

Interventions

The intervention used in the study were: Tasectan Plus - a Gelatine Xyloglucan CE mark Medical Device Plus ORS (Oral Rehidration Solution) versus ORS alone. Administration of the treatments was done according to products approved leaflets in each arm. The treatment duration was 5 days.

Intervention Type

Device

Primary outcome(s)

Occurence of AE

Key secondary outcome(s))

Reduction of stools

During the study we had 3 visits: Baseline visit, Visit 1 (2 days after baseline), Visit 2 (5 days after baseline). A telephone follow-up visit was performed at 10 days after Visit 2. The method used to measure the outcomes were by using a daily diary which has captured all the necessary information to measure the outcomes.

Completion date

15/02/2015

Eligibility

Key inclusion criteria

- 1. Children aged 3 months to 12 years with diagnosis of acute gastroenteritis (acute infectious diarrhoea); acute diarrhoea is defined as 'three or more liquid stools (rated 6 or 7 on Bristol Stool Scale) a day for less than 72 hours'
- 2. Patient with absent or mild-moderate dehydration which can be addressed through oral rehydration therapy (ORS)
- 3. Patient for whom oral rehydration therapy (ORS) and diet is considered the appropriate treatment by the treating physician

- 4. Patients for whom hospitalisation is not needed and can be treated in an out-patient setting
- 5. Patients for whom antibiotic therapy is considered not necessary by the treating physician
- 6. Informed consent signed by the legal representative of the child to participate in the clinical trial

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

3 months

Upper age limit

12 years

Sex

All

Key exclusion criteria

- 1. Infantile colic
- 2. Diarrhoea consequently to milk/protein intolerance
- 3. Severe dehydration needing intravenous rehydration
- 4. Need for hospitalisation
- 5. Use of antibiotics before the screening visit or need of antibiotics based on the clinical judgement of treating physician
- 6. Use of antidiarrheal treatment (antimotility, antisecretory, or adsorbent agents) before the screening visit or need of antidiarrheal agents based on the clinical judgement of treating physician
- 7. Chronic or toxic diarrhoea
- 8. Impossibility to follow the patient for more than 12 hours

Date of first enrolment

15/08/2014

Date of final enrolment

15/01/2015

Locations

Countries of recruitment

Romania

Study participating centre

Private Practice Dr. Pleasea Catalin Romania 805200

Study participating centre
Private Practice Dr. Nedelcu Steluta
Romania
810289

Study participating centre
Private Practice Dr. Opritescu Mirela
Romania
920055

Study participating centre Private Practice Dr. Plesea Alina Romania 800537

Study participating centre
Private Practice Dr. Ioan Muresan
Romania
400529

Study participating centre Private Practice Dr. Celia Tincau Romania 447020

Study participating centre Private Practice Dr. Livia Botic Romania 245600

Sponsor information

Organisation

Novintethical Pharma SA

ROR

https://ror.org/05ypvb778

Funder(s)

Funder type

Industry

Funder Name

Novintethical Pharma SA

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2016		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes