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

Submission date
24/06/2015

Recruitment status
No longer recruiting

Registration date
28/08/2015

Overall study status
Completed

Last Edited
24/05/2016

Condition category
Digestive System

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

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?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
2014-001814-24

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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 measure
Occurence of AE

Secondary outcome measures
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.

Overall study start date
15/07/2014

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

Age group
Child

Lower age limit
3 Months

Upper age limit
12 Years

Sex
Both

Target number of participants
36

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
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Study participating centre
Private Practice Dr. Celia Tincau
Romania
447020

Study participating centre
Private Practice Dr. Livia Botic
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245600

Sponsor information

Organisation
Novintethical Pharma SA

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Sponsor type
Industry

Website
http://www.novintethical.com

ROR
https://ror.org/05ypvb778

Funder(s)

Funder type
Industry

Funder Name
Novintethical Pharma SA

Results and Publications

Publication and dissemination plan
At least one article will be prepared and published in a scientific journal in 2015.

Intention to publish date
01/12/2015

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