

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

<b>Submission date</b> 24/06/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 28/08/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 24/05/2016	<b>Condition category</b> Digestive System	<input type="checkbox"/> 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 child's 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 Mihai  
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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 Rehydration 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**

Occurrence 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 consequent 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. Opretescu 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

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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?
<a href="#">Results article</a>	results	01/01/2016		Yes	No