ISRCTN90311828 https://doi.org/10.1186/ISRCTN90311828

Safety and efficacy and rapidity of action of Tasectan Plus vs Diosmectite and vs S. Bouliardii in the treatment of acute diarrhea

Submission date
02/06/2015

Recruitment status
No longer recruiting

Registration date
11/06/2015

Overall study status
Completed

Last Edited
13/07/2016

Condition category
Digestive System

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

Plain English summary of protocol
Plain English summary under review

Contact information

Type(s)
Scientific

Contact name
Mr Manolache Mihai

Contact details
222nd Calea Plevnei 3rd Floor
Bucharest
Romania
060016
+40 (0)731834503
mihai.manolache@cebis-int.com

Additional identifiers

Protocol serial number
NC_TAS_011012

Study information

Scientific Title

Safety and efficacy and rapidity of action of Tasectan Plus vs Diosmectite and vs S. Bouliardii in the treatment of acute diarrhea: multicenter, randomized, open label, parallel group, controlled clinical study

Study objectives
1. Is Tasectan Plus safer than Diosmectite and S. boulardii?
2. Is Tasectan Plus more efficient than Diosmectite and S. boulardii?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Med trial research, 01/11/2013, ref: 31

Primary study design
Interventional

Study design
Multicenter open-label parallel-group active treatment controlled randomized clinical study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Diarrhea

Interventions
Tasectan Plus vs Diosmectite vs S. boulardii

Patients fulfilling the inclusion criteria will be recruited by family doctors during their normal daily practice and randomised for a 2 day treatment. The study duration is expected to be at least 3 days
or maximum 10 days.

Intervention Type
Device

Primary outcome(s)
Frequency of AE/SAE in each arm

Key secondary outcome(s)
Efficacy will be evaluated as following:
The patients will assume the first treatment dose at time of recruitment, i.e. already at the doctor's office and will be trained for the self-administration of an ad-hoc symptoms questionnaire to record their stools and symptoms at 1, 3, 6, 12, 24 and 48 hours following the first study dose.
The symptoms recorded will be objective (stools, vomiting and fever) and subjective (nausea, abdominal pain, and bloating). The stools grading will be according to the Bristol scale, presence of mucus and blood will be also recorded. The intensity of subjective symptoms will be graded by a VAS.

Completion date
01/06/2014

Eligibility

Key inclusion criteria
1. Informed consent
2. Subjects of both sex aged over 18
3. Presence of diarrhea defined as occurrence of > 3 stools per day graded 6 or 7 on the Bristol scale

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Allergy to one of the product ingredients
2. Pregnant women or breastfeeding
3. Recent surgery
4. Serious and/or systemic diseases

Date of first enrolment
25/11/2013

Date of final enrolment
15/04/2014

Locations

Countries of recruitment
Romania

Study participating centre
University of Medicine & Pharmacy Targu-Mures
Romania
540139

Study participating centre
Dr. Pleasea Condratovici Catalin Private Practice
Galati
Romania
805200

Study participating centre
Dr. Nedelcu Steluta Private Practice
Galati
810289

Study participating centre
Dr. Rosoga Natalia Private Practice
Targu Jiu
Romania
210166

Study participating centre
Dr. Gavanescu Mihaela Private Practice
Bucharest
031753

Sponsor information

Organisation
Novintethical Pharma

ROR
https://ror.org/05ypvb778

Funder(s)

Funder type
Industry

Funder Name

Novitethical 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	30/10/2015		Yes	No