

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	☐ Prospectively registered ☐ Protocol
Registration date 11/06/2015	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 13/07/2016	Condition category Digestive System	☐ Individual participant data

Plain English summary of protocol

Plain English summary under review

Contact information

Type(s)

Scientific

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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. bouliardii?
2. Is Tasectan Plus more efficient than Diosmectite and S. bouliardii?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Med trial research, 01/11/2013, ref: 31

Study design

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

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Diarrhea

Interventions

Tasectan Plus vs Diosmectite vs S. bouliardii

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

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