A Phase I, Single-Centre, Randomized, Double-Blind, Placebo Controlled, Multiple Dose Study to Evaluate the Effect of tedalinab on ECG parameters, CNS Function and Pain Perception in Healthy Subjects.

Published: 15-06-2010
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Evaluate the effect of tedalinab on ECG parameters, CNS Function and Pain Perception in Healthy Subjects.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Peripheral neuropathies
Study type	Interventional

Summary

ID

NL-OMON34384

Source
ToetsingOnline

Brief title
Phase I study to evaluate effects of tedalinab

Condition

- Peripheral neuropathies

Synonym
Chronic pain

Research involving
Human

Sponsors and support

Primary sponsor: Glenmark Pharmaceuticals
Source(s) of monetary or material Support: Glenmark Pharmaceuticals SA

Intervention

Keyword: effect, multiple dose, phase I, tedalinab

Outcome measures

Primary outcome

Adverse events, pharmacokinetics results, ECG parameters

Secondary outcome

Cognitive function, pain perception and plasma beta-endorphin levels

Study description

Background summary

In animal toxicology studies, tedalinab was shown to slow heart rate and to increase corrected QT interval (QTc) in all species (rat, monkey and dog) studied. Animals in these trials were exposed at levels at least 5 fold higher than those reached in studies in humans. In early human trials, ECG evaluations failed to show a clear effect on QTc interval, however receipt of tedalinab appeared to be associated with reductions in heart rate, most notable within 2 hours of dosing and noted more frequently during the multiple dose study. This study is being performed to evaluate the effect, if any, of tedalinab on cardiac intervals including QTc, using beat to beat analysis, which is thought to be more appropriate for evaluating potential effects of compounds which have an effect on heart rate.

Study objective

Evaluate the effect of tedalinab on ECG parameters, CNS Function and Pain Perception in Healthy Subjects.

Study design

Phase I, Single-Centre, Randomized, Double-Blind, Placebo Controlled, Multiple

Dose

Intervention

Three different tedalinab dose regimens or matching placebo
Capsaicin/electrical evoked pain test
Cognitive test battery

Study burden and risks

The risks associated with this investigation are linked together with the possible side effects of the investigational product (most important reported adverse events were: skin rash, headache, dizziness and somnolence).
The burden on the volunteer will be the holter ECG monitoring, neuropsychological tests, electrical pain treshold and tolerance test, capsaicin evoked pain test, the venapunctions and the introduction of the cannulas. All volunteers are closely monitored and supervised by experienced doctors and study staff for possible side effects.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Male, 18-65 years (inclusive);
• Body weight >=60kg;
• Physical examination and laboratory safety evaluations within normal range for age;
• Willing to participate and provide written informed consent.

Exclusion criteria

• Allergy to tedalinab or any excipients;
• Subjects who have participated in an investigational drug study within 90 days prior to the dosing day;
• Hepatitis B, C or HIV infection;
• Subjects who have lost or donated >350 ml of blood within 12 weeks prior to the (first) dosing day;
• Subjects with clinically significant laboratory abnormalities;
• Subjects with an abnormal ECG at Screening or pre-dose, defined as:
o PR > 210 ms, or QRS complex > 120 ms, or QTc > 450 ms;
o Any cardiac conduction abnormalities;
o Any known structural abnormalities;
o Any clinically significant ST/T wave abnormalities;
o Any atrial or ventricular arrhythmias which are of clinical significance and may have an impact on the safety of the subject or the conduct of the study as judged by the PI;
• Subjects with a history of additional risk factors for torsade de pointes, e.g. a personal or family history of Long QT Syndrome;
• Subjects with a supine systolic blood pressure >160 mmHg or a supine diastolic blood pressure >90 mmHg;
• Subjects with a Body Mass Index (BMI) <18.0 or >29.0 kg/m2;
• Subjects who smoke (subjects will have to be non-smokers for at least 6 months preceding Screening);
• Subjects who have used prescription medication within 2 weeks prior to the first dosing day;
• Subjects who have used non-prescription medication, including aspirin, paracetamol, homeopathic medicines, vitamins, and herbal and dietary supplements within 96 hours pre-dose;
• Subjects with a presence or a history of clinically relevant conditions in the gastrointestinal, hepatic, renal, urogenital, metabolic, endocrine or central and peripheral nervous systems;
• Subjects with active presence or history of alcoholism or drug addiction;

• Subjects who are considered unsuitable to participate in the study for any reason in the opinion of the PI.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-07-2010
Enrollment:	80
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Tedalinab
Generic name:	Tedalinab

Ethics review

Approved WMO

Date:	15-06-2010
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO

Date:	21-06-2010
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2010-021010-32-NL
CCMO	NL32692.056.10