A single-center, open-label, randomized, two-period, two-treatment, crossover study in healthy male subjects to demonstrate bioequivalence of 1600 mcg selexipag administered as eight tablets of 200 mcg (reference drug) or as single tablet of 1600 mcg (test drug)

Published: 28-08-2012
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- To demonstrate bioequivalence of test drug and reference drug - Safety and tolerability- Investigate phamacokinetic properties of selexipag and its metabolite

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Pulmonary vascular disorders
Study type	Interventional

Summary

ID

NL-OMON37306

Source
ToetsingOnline

Brief title
Selexipag / ACT-293987 bioequivalence study

Condition

- Pulmonary vascular disorders

Synonym
pulmonary arterial hypertension

Research involving
Human

Sponsors and support

Primary sponsor: Actelion Pharmaceuticals
Source(s) of monetary or material Support: ACTELION Pharmaceuticals Ltd

Intervention

Keyword: bio equivalence, cross-over, healthy men, open label

Outcome measures

Primary outcome

Pharmacokinetics

Secondary outcome

Safety and tolerability

Study description

Background summary

The research medication is a medication under development for the treatment of pulmonary arterial hypertension (PAH)

Study objective

- To demonstrate bioequivalence of test drug and reference drug
- Safety and tolerability
- Investigate phamacokinetic properties of selexipag and its metabolite

Study design

This is a prospective, single-center, open-label, randomized, two-period, two-treatment, crossover, multiple-dose, up titration, phase 1, bioequivalence study.

Intervention

The study will start with a screening At the screening a physical examination will take place and a few other standard medical assessments will be performed (Vital Signs, ECG). Furthermore a blood and urine sample will be taken for laboratory tests and an alcohol breath test and drug screen will be done. During the stay in the clinic and ambulant visits the subject will receive the study medication and on several time points blood will be taken. The subjects will be asked for possible side effects on a regular basis. Furthermore several safety assessments will be done frequently

Finally a follow up visit will take place

Study burden and risks

Data from Phase I studies with selexipag indicated that multiple doses up to 1600 µg bid were well tolerated. In a phase 2a study selexipag was well tolerated and the safety profile was in-line with the expected pharmacologic effect.
Reported side effects in previous studies were headache, dizziness, diarrhea, nausea, vomiting, jaw pain, pain in extremity, myalgia, arthralgia, flushing and cough.

The blood collection may cause discomfort or bruising. Occasionally, fainting, an infection at the blood sampling site, bleeding and blood clot formation can occur.

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

• Healthy male subjects aged between 18 and 55 years (inclusive)
• No clinically significant findings at Screening.
• Body mass index (BMI) of 18.0 to 30.0 kg/m2 (inclusive) at Screening.
• Systolic blood pressure (SBP) 100-145 mmHg, diastolic blood pressure (DBP) 50-90 mmHg, and pulse rate (PR) 45-90 bpm (inclusive);Refer to protocol for complete list of inclusion criteria

Exclusion criteria

• Known allergic reactions or hypersensitivity to selexipag
• History or clinical evidence of any clinical significant disease and/or existence of any surgical or medical condition.
• History or clinical evidence of alcoholism or drug abuse
• Excessive caffeine consumption;Refer to protocol for a complete list of exclusion criteria

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-09-2012
Enrollment:	124
Type:	Anticipated

Ethics review

Approved WMO Date:	28-08-2012
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	31-08-2012
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	17-12-2012
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	27-12-2012
Application type:	Amendment
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	EUCTR2012-002673-66-NL
CCMO	NL41665.056.12