Prospective, single-center, randomized, double-blind, placebo-controlled, two-part Phase 1 study to assess the effect of single therapeutic and supra-therapeutic doses of lucerastat on the QT/QTc interval duration in healthy subjects

Published: 08-01-2019
Last updated: 12-04-2024

Primary objectivePart A* To determine the supra-therapeutic dose of lucerastat to be used in Part B.Part B* To demonstrate that lucerastat does not have an effect on the QT interval corrected for heart rate (QTc) interval exceeding 10 ms using...

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

Summary

ID

NL-OMON48323

Source
ToetsingOnline

Brief title
CS0311 (ID-069-106)

Condition

- Other condition

Synonym
Fabry disease, Lysosomal storage disease

Health condition

Metabolic disorder - Lysosomal storage disease

Research involving
Human

Sponsors and support

Primary sponsor: Idorsia Pharmaceuticals Ltd
Source(s) of monetary or material Support: Idorsia Pharmaceuticals Ltd.

Intervention

Keyword: double-blind, Lucerastat, randomized, thorough QT study

Outcome measures

Primary outcome

cardiodynamic variables

Secondary outcome

Pharmacokinetic, safety and tolerability endpoints

Study description

Background summary

Lucerastat is being developed for the treatment of Fabry disease, a rare hereditary disorder. Fabry disease is a so-called lysosomal storage disorder.

Study objective

Primary objective

Part A
* To determine the supra-therapeutic dose of lucerastat to be used in Part B.

Part B
* To demonstrate that lucerastat does not have an effect on the QT interval corrected for heart rate (QTc) interval exceeding 10 ms using concentration-QTc analysis.

Study design

Prospective, single-center, randomized, double-blind, placebo-controlled, two-part Phase 1 study to assess the effect of single therapeutic and supra-therapeutic doses of lucerastat on the QT/QTc interval duration in healthy subjects

Intervention

Lucerastat, moxifloxacin or placebo

Study burden and risks

The risk to health at the chosen dose is limited, but the volunteers may experience any of the side effects written in the ICF or symptoms that have not been reported before.

Volunteers health is closely monitored during the study to minimize these risks.

If the volunteers experience side effects, the investigator will treat them where necessary. If new information is available on the safety of the study medication, the volunteers are informed as soon as possible. The blood collection procedure is not dangerous.

Contacts

Public
Idorsia Pharmaceuticals Ltd

Hegenheimermattweg 91
Allschwil CH-4123
CH
Scientific
Idorsia Pharmaceuticals Ltd

Hegenheimermattweg 91
Allschwil CH-4123
CH

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Part A only
1. Healthy male subjects aged between 18 and 55 years (inclusive) at Screening.;Part B only
2. Healthy male and female subjects aged between 18 and 55 years (inclusive) at Screening.;Part A and B
3. Signed informed consent in a language understandable to the subject prior to any study-mandated procedure.
4. Body mass index of 18.0 to 30.0 kg/m2 (inclusive) at Screening. Body weight at least 50.0 kg at Screening and prior to first study treatment administration.;Further inclusion criteria can be found in the protocol section 3.2.2

Exclusion criteria

Part B only
1. Known hypersensitivity to moxifloxacin or any of its excipients. ;Part A and B
2. Previous exposure to lucerastat.
3. Known hypersensitivity to any of lucerastat*s excipients.
4. Known hypersensitivity or allergy to natural rubber latex.;Further exclusion criteria can be found in the protocol section 3.2.3.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial

Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-02-2019
Enrollment:	44
Type:	Actual

Ethics review

Approved WMO Date:	08-01-2019
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO Date:	16-01-2019
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	EUCTR2018-004546-42-NL
CCMO	NL68517.056.18