A phase 1, randomized, double-blind, placebo-controlled, single- and multiple-dose escalation study evaluating safety and pharmacokinetics of VX-150 including an assessment of the effect of food on the pharmacokinetics of VX-150 in healthy adult subjects.

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

Summary

ID

NL-OMON41908

Source
ToetsingOnline

Brief title
VX-150 SAD/MAD/FE Study

Condition

- Other condition

Synonym
Pain.

Health condition

Pijn.

Research involving
Human

Sponsors and support

Primary sponsor: Vertex Pharmaceuticals Incorporated
Source(s) of monetary or material Support: Farmaceutische Industrie.

Intervention

Keyword: Pain, VX-150

Outcome measures

Primary outcome

Safety and tolerability of single doses of VX-150.

Safety and tolerability of multiple doses of VX-150.

Secondary outcome

n.a.

Study description

Background summary

VX 150 (also called study drug) is a new investigational drug. Investigational means the study drug is not approved for use and is still being tested for safety and effectiveness. This study drug may eventually be used for the treatment of pain. VX 150 is a blocker of sodium (Na) channels, specifically the NaV1.8 channel. Sodium channels are channels present in the outer layer of cells, which allow sodium ions to enter the cell in certain circumstances. The NaV1.8 channel is primarily present in neurons that sense pain and it plays an important role in pain signaling. This is the first time that this study drug is being given to humans.

Study objective

The study will be performed in 2 parts, Parts A and B.
The purpose of Part A of the study is to investigate the safety of VX 150 and to what extent a single dose of VX 150 is tolerated. It will also be investigated how quickly and to what extent a single dose of VX 150 is absorbed and eliminated from the body (this is called pharmacokinetics). In addition, the effect of food on the pharmacokinetic properties of VX 150 will be investigated.
The purpose of Part B of the study is to investigate the safety of VX 150 and to what extent multiple doses of VX 150 are tolerated, and how quickly and to what extent multiple doses of VX 150 are absorbed and eliminated from the body.

Study design

For Groups 1, 2, 3, 5, and 6 the actual study will consist of 1 period during which the volunteers will stay in the clinical research center in Groningen for 6 days (5 nights). If they participate in Group 4/7 they will stay in the clinical research center in Groningen for 1 period during which they will stay in the clinical research center in Groningen for 16 days (15 nights).

Groups 1, 2, 3, 5, and 6
During the study, the volunteers will receive VX 150 or placebo as an oral solution with 240 milliliters of tap water. Immediately before and after study drug dosing they will be allowed to use a taste masking solution to mask the taste of the study drug. They will receive the study drug after an overnight fast (at least 8 hours no meal). For all groups it is applicable that on Day 1 fasting will continue until 4 hours after study drug administration. Then they will receive a lunch. During fasting and after study drug administration they are allowed to drink water with the exception of 2 hours prior to dosing until 2 hours after dosing.

Group 4/7
On Day 1 the volunteers will receive VX 150 or placebo as an oral solution with 240 milliliters of tap water after an overnight fast (at least 8 hours no meal). Immediately before and after study drug dosing they will be allowed to use a taste masking solution to mask the taste of the study drug.
On Day 6 and Day 11 they will receive VX 150 as a tablet with 240 milliliters of tap water. After intake of the tablet, one of the investigators will inspect the hands and mouth. On Day 6 they will receive VX 150 after an overnight fast (at least 8 hours no meal) and on Day 11 they will receive the study drug 30 minutes after a breakfast. During fasting and after study drug administration the volunteers are allowed to drink water with the exception of 2 hours prior to dosing until 2 hours after dosing.

Intervention

Group

1: 1 x 25 mg VX 150 or placebo, once
2: 1 x X mg VX 150 or placebo, once
3: 1 x X mg VX 150 or placebo, once
4/7: 1 x X mg VX 150 or placebo en 3 x X mg VX 150 once
5: 1 x X mg VX 150 or placebo, once
6: 1 x X mg VX 150 or placebo, once

Study burden and risks

All potential drugs cause adverse events; the extent to which this occurs differs. As VX 150 will be administered to humans for the first time in this study adverse effects of VX 150 in humans have not been reported to date. However, VX 150 has been studied in laboratory animals (rats and monkeys) that have not demonstrated any harmful side effects or toxicities at any tested dose level. Decreased body weight and lower food consumption were observed in rats exposed to high doses of the study drug.

Procedures: Pain, light bleeding, hemeatoma and possible an infection.

Contacts

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Scientific
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US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Healthy male or female volunteers
18 and 55 years of age, inclusive
BMI 18.0 - 31.0 kilograms/meter2

Exclusion criteria

Suffering from hepatitis B, hepatitis C, cancer or HIV/AIDS. In case of participation in another drug study within 90 days before the start of this study or being a blood donor within 60 days from the start of the study. In case of donating more than 1.5 liters of blood in the 10 months prior the start of this study.

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):	28-01-2015
Enrollment:	96
Type:	Actual

Ethics review

Approved WMO Date:	15-01-2015
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	26-01-2015
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	12-03-2015
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	27-05-2015
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	EUCTR2014-002924-29-NL
CCMO	NL52002.056.15