A Phase 1, Randomized, Double-blind, Placebo controlled, Crossover Study to Evaluate the Pharmacodynamic Effects of VX*150 in Healthy Male Adults

Published: 18-12-2017
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To investigate the analgesic properties of VX-150 in healthy adult male volunteers using a panel of pain tests

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neurological disorders NEC
Study type	Interventional

Summary

ID

NL-OMON46528

Source
ToetsingOnline

Brief title
PD study in healthy adults using VX-150

Condition

- Neurological disorders NEC

Synonym
Pain

Research involving
Human

Sponsors and support

Primary sponsor: Vertex Pharmaceuticals
Source(s) of monetary or material Support: Funded by sponsor

Intervention

Keyword: Analgesic, Pharmacodynamics, Safety

Outcome measures

Primary outcome

PD endpoints from panel of pain tests:

- PTT in electrical stimulation, pressure, and cold pressor pain tests

- PDT in thermal pain and capsaicin-induced pain tests

Secondary outcome

-Safety and tolerability, based on the assessment of AEs, clinically

significant laboratory test results, standard 12 lead ECGs, and vital signs

-PK parameter estimates of VRT-1207355

-VRT-1207355 concentrations in CSF

Study description

Background summary

This is a study evaluating the analgesic properties of VX-150 in healthy adult male volunteers.

Study objective

To investigate the analgesic properties of VX-150 in healthy adult male volunteers using a panel of pain tests

Study design

A study evaluating single dose VX-150 PD using a cross-over design

Intervention

VX-150 or matching placebo

Study burden and risks

Based on review of nonclinical and clinical safety findings, there are adequate safety margins to initiate the study and evaluate the proposed dose . Safety monitoring specified in the protocol is adequate to ensure the safety of human subjects. The safety profile of VX-150 has been informed by 4 completed Phase 1 and one completed Phase 2 study and supports evaluation of the proposed dose used in this study.

Contacts

Public
Vertex Pharmaceuticals

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Boston MA, 02210
US
Scientific
Vertex Pharmaceuticals

Northern Avenue 50
Boston MA, 02210
US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1.Subject will sign and date an informed consent form (ICF).

2.Willing and able to comply with scheduled visits, treatment plan, study restrictions laboratory tests, contraceptive
guidelines, and other study procedures.
3. Male subjects will be between the ages of 18 and 55 years, inclusive, and healthy, as defined by no clinically relevant abnormalities identified by a detailed medical history, physical examination (PE) of all body systems, including blood pressure and pulse rate measurement, standard 12 lead ECG, and clinical laboratory tests.
4. Body mass index (BMI) of 18.0 to 38.0 kg/m2, inclusive, and a total body weight >50 kg.

Exclusion criteria

1.History of any illness or any clinical condition that, in the opinion of the investigator, might confound the results of
the study or pose an additional risk in administering study drug to the subject. This may include, but is not limited
to, history of relevant drug or food allergies; history of cardiovascular or central nervous system disease; history or
presence of clinically significant pathology; clinically significant history of mental disease; and history of cancer,
except for squamous cell skin cancer, basal cell skin cancer, and Stage 0 cervical carcinoma in situ (all 3 with no recurrence for the last 5 years).
2.History of febrile illness within 5 days before the first study drug dose.
3.A screen positive for hepatitis B surface antigen (HBsAg), hepatitis C virus (HCV) antibody, or antibodies against human immunodeficiency viruses 1 and 2 (HIV 1/HIV 2 Abs).
4.Any condition possibly affecting drug absorption (e.g., gastrectomy, cholecystectomy, or other gastrointestinal tract surgery, except appendectomy).
5.Standard 12 lead ECG demonstrating QTcF >450 msec at screening. If QTcF exceeds 450 msec, the ECG will be repeated 2 more times, and the average of the 3 QTcF values will be used to determine the subject*s eligibility.
6.History of cardiac dysrhythmias requiring anti-arrhythmia treatment(s); or history or evidence of abnormal ECGs that, in the opinion of the investigator or medical monitor, would preclude the subject*s participation in the study.
7.Male subjects with a female partner who is planning to become pregnant during the study or within 90 days after the last study drug dose.
8.Blood donation (of approximately 1 pint [500 mL] or more) or any significant loss of blood within 90 days before the first study drug dose, as determined by the investigator.
9.Use of restricted medication or food within the specified duration before the first dose of study drug, as defined in Table 9 1.
10.Enrollment in a previous cohort or part in this study.
11.History of regular alcohol consumption exceeding 21 drinks per week within 6 months before screening (1 drink equals 5 ounces/150 mL of wine, 12 ounces/360 mL of beer, or 1.5 ounces/45 mL of hard liquor)
12.A positive test for alcohol.
13.A history of drug abuse or dependence (according to DSM-IV criteria) within 2 years before the first dose of study drug or a screen positive for drugs of abuse as defined in Section

11.6.2.
14.Subject, or close relative of the subject, is the investigator or a subinvestigator, research assistant, pharmacist, study coordinator, or other staff directly involved with the conduct of the study at that site.
15.Any current, clinically significant, known medical condition in particular any existing conditions that would affect sensitivity to cold (such as atherosclerosis, Raynaud*s disease, urticaria, hypothyroidism) or pain (i.e., disease that causes pain, hypesthesia, hyperalgesia, allodynia, paraesthesia, neuropathy)
16.Subjects indicating pain tests intolerable at screening or achieving tolerance at > 80% of maximum input intensity for any pain test for cold, pressure and electrical tests.

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):	31-01-2018
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	18-12-2017
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO

Date:	10-01-2018
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	EUCTR2017-004786-27-NL
CCMO	NL64285.056.17