A Phase 1, Randomized, Double-blind, Placebo-controlled Trial to Determine the Pharmacodynamics and Pharmacokinetics of OPC-214870 Following Repeated Oral Administration to Healthy Subjects

Published: 12-07-2022
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- To assess the CNS functional effects of OPC-214870 following dosing using Neurocart test battery

Ethical review	Approved WMO
Status	Will not start
Health condition type	Seizures (incl subtypes)
Study type	Interventional

Summary

ID

NL-OMON51813

Source
ToetsingOnline

Brief title
Pharmacokinetics and pharmacodynamics of OPC-214870 in healthy volunteers

Condition

- Seizures (incl subtypes)

Synonym
Epilepsy, seizures

Research involving
Human

Sponsors and support

Primary sponsor: Otsuka Pharmaceutical Development & Commercialization, Inc.
Source(s) of monetary or material Support: Pharmaceutical industry

Intervention

Keyword: Healthy Subjects

Outcome measures

Primary outcome

Pharmacodynamic: The assessments include questionnaires and tests on vigilance,

attention and eye-hand coordination, among various other tests.

Pharmacokinetic: OPC-214870 plasma concentrations, AUC0-24h, and Cmax

Secondary outcome

• Reported AEs, vital sign measurements, ECGs, clinical laboratory tests,

physical examinations, neurological examinations, the C-SSRS, and pulmonary

function tests.

Study description

Background summary

The pharmacology of OPC-214870 has been characterized using both in vitro and in vivo models. OPC-214870 may represent a potential treatment option for seizure disorders. Results suggest that OPC-214870 may represent a potential treatment option for seizure disorders that warrants further investigation. This clinical trial seeks to better understand the pharmacodynamic effects OPC-214870 has not been fully elucidated. In this regard, the translatability of the nonclinical findings will be further investigated using CHDR Neurocart battery and also whether the PD endpoints obtained are similar or different from known antiseizure medications.
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Study objective

- To assess the CNS functional effects of OPC-214870 following dosing using Neurocart test battery

Study design

This is a phase 1, randomized, double-blind, placebo-controlled trial to determine the pharmacodynamics (PD) and pharmacokinetics (PK) of OPC-214870 following repeated dosing in healthy adult subjects.

Intervention

OPC-214870 (3 dose strengths) tablets or matching placebo tablets once daily for 8 consecutive days.

Study burden and risks

Overall, OPC-214870 has been safe and well-tolerated in phase 1 clinical trials. No serious adverse events (SAEs) were reported for single doses from 10 mg to 1000 mg. OPC-214870 administered as multiple ascending doses was well tolerated. The AEs in subjects receiving single or multiple doses of OPC-214870 were mainly associated with the central nervous system (CNS) and were mild or moderate in severity. The NeuroCart is considered minimally burdensome but still sensitive to the PD effects of a vast array of different CNS active drugs. Overall the burden and risks associated with this study are considered acceptable and justifiable. The primary goal of this study is to investigate the pharmacodynamics of OPC-214870 therefore the trial population will consist of healthy males and females, 18 to 55 years of age, inclusive.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

1) Male or female subjects between 18 and 55 years of age, inclusive.
2) Body mass index (BMI) between 19.0 to 32.0 kg/m2 (inclusive).
3) In good health as determined by:
a) Medical history
b) Physical examination
c) Neurological examination
d) Vital signs
e) Electrocardiogram (ECG)
f) Spirometry
g) Serum/urine biochemistry, hematology, and serology tests.
4) Ability to provide written, informed consent prior to initiation of any trial-related procedures, and ability, in the opinion of the principal investigator, to comply with all the requirements of the trial.

Exclusion criteria

1) Females who are breast-feeding and/or who have a positive pregnancy test result prior to receiving investigator medicinal product
2) Sexually active men or women of childbearing potential (WOCBP), or their partners, who do not agree to practice 2 different approved methods of birth control (ie, vasectomy, tubal ligation, nonhormonal intrauterine device, condom with spermicide, sponge with spermicide, or occlusive cap [vaginal diaphragm or cervical/vault cap] with spermicide) or remain fully abstinent (periodic abstinence [eg, calendar, ovulation, symptothermal, postovulation methods] or withdrawal are not acceptable methods of contraception) during the trial and for 90 days after the last dose of IMP. If employing birth control, male subjects must use condom with spermicide plus one of the approved methods.

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:	Will not start
Start date (anticipated):	26-08-2022
Enrollment:	24
Type:	Actual

Ethics review

Approved WMO Date:	12-07-2022
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	26-08-2022
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	EUCTR2022-001826-31-NL
CCMO	NL81722.056.22