An open-label, multiple oral dose study to investigate the plasma and CSF pharmacokinetics of CAD-1883 in healthy volunteers

Published: 10-09-2019
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Primary ObjectiveTo determine the plasma and cerebrospinal fluid (CSF) pharmacokinetic (PK) profile of multiple oral doses of CAD-1883 in healthy subjects.Secondary ObjectiveTo evaluate the safety and tolerability of multiple oral doses of CAD-1883...

Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON47994

Source
ToetsingOnline

Brief title
Oral dose of CAD-1883

Condition

- Other condition

Synonym
essential tremor (ET), Spinocerebellar ataxia (SCA)

Health condition

movement disorders

Research involving

Human

Sponsors and support

Primary sponsor: Cadent Therapeutics Inc.
Source(s) of monetary or material Support: Cadent Therapeutics Inc.

Intervention

Keyword: CAD-1883, CSF, PK

Outcome measures

Primary outcome

Pharmacokinetic parameters of CAD-1883 including Cmax, tmax, Cmin, Cavg, *z,

t1/2, AUC0-t, AUC0-inf, AUC0-tau, AUCextra, CL/F, Vz/F, and AR in plasma.

Pharmacokinetic parameters of CAD-1883 including Cmax, tmax, *z, t1/2, AUC0-t,

AUC0-inf and AUCextra in CSF.

Secondary outcome

Safety parameters include adverse events (AE), physical examination, clinical

laboratory values, vital signs, orthostatic vital signs, 12-lead ECG, and

C-SSRS scores.

Study description

Background summary

CAD-1883 is a novel, first-in-class, small-molecule, positive allosteric modulator of small- conductance calcium-activated potassium channels (SK channels) which is being developed for the treatment of spinocerebellar ataxia (SCA) and essential tremor (ET).

Study objective

Primary Objective
To determine the plasma and cerebrospinal fluid (CSF) pharmacokinetic (PK)

profile of multiple oral doses of CAD-1883 in healthy subjects.

Secondary Objective
To evaluate the safety and tolerability of multiple oral doses of CAD-1883 in healthy subjects.

Exploratory Objective
To determine kidney injury biomarkers in urine (results will be reported separately).

Study design

This is a single site, open-label, multiple oral dose study in 1 cohort of healthy subjects.
After assessing eligibility during a screening period of up to 4 weeks, 8 subjects will be included.
Subjects will check into the clinic one day prior to first dosing (Day -1).
Subjects will be released from the clinic on Day 16 after all required study procedures are completed and if medically justified.
Each subject will receive 600 mg CAD-1883 BID from Day 1 up to and including Day 14. Dosing is scheduled at approximately midnight and approximately 8:00 AM.
Upon completion of the treatment period, or early withdrawal, subjects will return to the clinic approximately 7 days after the last dosing of study drug for a follow-up visit.

Intervention

CAD-1883

Study burden and risks

Since the study is being executed in healthy volunteers, there are no anticipated benefits of the IMP. Please see the IMPD for further information.

Contacts

Public
Cadent Therapeutics Inc.

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US
Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Subject is male or female of non-childbearing potential, aged between 50 and 65 years (inclusive).
BMI of *18.0 kg/m2 and * 30.0 kg/m2 at Screening.
Healthy as determined by the Investigator, based upon a medical evaluation including medical history, physical examination, neurological examination, lab tests and ECG performed at Screening.

Please refer to the protocol for more inclusion criteria

Exclusion criteria

Prior or ongoing medical condition, medical history, physical findings, ECG findings, laboratory or vital signs abnormality that, in the Investigator*s opinion, could adversely affect the safety of the subject.
History of physician diagnosed hereditary ataxia or tremor.
History of clinically significant drug allergies.

Please refer to the protocol for more exclusion criteria

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	31-10-2019
Enrollment:	8
Type:	Actual

Ethics review

Approved WMO Date:	10-09-2019
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	01-10-2019
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	05-12-2019
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	EUCTR2019-003471-18-NL
CCMO	NL71292.056.19

Study results

Date completed: 22-11-2019

Results posted: 03-03-2021

First publication
05-08-2020