Interventional, open-label, exploratory study, investigating the safety, tolerability, pharmacokinetics, and efficacy of Lu AF28996 in patients with Parkinson*s disease

Published: 11-12-2019
Last updated: 10-04-2024

Main objectives:To evaluate the safety and tolerability of Lu AF28996 after up-titration of oral dose(s) in patients with Parkinson's Disease (PD)To investigate the pharmacokinetic properties of Lu AF28996 after up-titration of oral dose(s) in...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Movement disorders (incl parkinsonism)
Study type	Interventional

Summary

ID

NL-OMON52830

Source
ToetsingOnline

Brief title
CS0334 Lundbeck (18252A)

Condition

- Movement disorders (incl parkinsonism)

Synonym
Parkinson's disease

Research involving
Human

Sponsors and support

Primary sponsor: H. Lundbeck A/S
Source(s) of monetary or material Support: H. Lundbeck A/S

Intervention

Keyword: pharmacokinetics, safety, tolerability

Outcome measures

Primary outcome

1. Number of participants with treatment-emergent adverse events.

Safety and tolerability based on the safety assessments (clinical safety laboratory tests, vital signs, weight, ECG parameters and physical examination).

2. Cmax Lu AF28996.

Maximum observed plasma concentration of Lu AF28996.

3. AUC(0-24h) Lu AF28996.

Area under the plasma concentration time curve from zero to infinity.

4. CL/F Lu AF28996

Oral clearance for Lu AF28996 in plasma.

Secondary outcome

N/A

Study description

Background summary

Lu AF28996 has been administered to healthy volunteers before, but is not registered as a medicine. It is a compound that is being developed for the treatment of Parkinson*s disease. Parkinson*s disease is a brain disorder in

which the control of certain muscle movements by the brain is affected. This is because in this disease the cells that produce dopamine, a substance that transmits signals between cells, in the brain slowly die. The resulting dopamine deficit can cause tremors and motor impairments as well as other cognitive symptoms. Lu AF28996 mimics the activity of dopamine and can therefore potentially be used for the treatment of Parkinson*s disease.

Study objective

Main objectives:
To evaluate the safety and tolerability of Lu AF28996 after up-titration of oral dose(s) in patients with Parkinson's Disease (PD)
To investigate the pharmacokinetic properties of Lu AF28996 after up-titration of oral dose(s) in patients with PD

Study design

This is an interventional, open-label, exploratory study, investigating the safety, tolerability, pharmacokinetics, and efficacy of Lu AF28996 in patients with Parkinson*s disease.

12 patients are planned for enrollment, but, if deemed necessary, up to 15 patients can be enrolled. Patients will be recruited from specialist settings within PD.
The study will, for this study design, comprise 3 cohorts (Cohorts 2-4) and include 3 patients in Cohort 2 and 4 patients (men or women) in both Cohorts 3 and 4, with the possibility of adding 1 more cohort (Cohort 5) including 4 patients. All cohorts will be open-label, sequential cohorts.

Intervention

Lu AF28996 hard capsules

Study burden and risks

There are no distinct benefits for participating in this study. Your participation will provide information about the study drug. This might benefit others in the future. Disadvantage of participation in the study may be the discomforts of the tests performed in the study and the occurrence of side effects.

Contacts

Public

H. Lundbeck A/S

Ottiliavej 9 Ottiliavej 9
Valby DK-2500 Valby
DK
Scientific
H. Lundbeck A/S

Ottiliavej 9 Ottiliavej 9
Valby DK-2500 Valby
DK

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- The patient is able to read and understand the Subject Information Sheet and Informed Consent Form.
- The patient has signed the study-specific Informed Consent Form.
- The patient is diagnosed with idiopathic Parkinson*s disease (consistent with the UK Parkinson*s Disease Society Brain Bank Criteria for the Diagnosis of PD) and should not have more than 1 first-degree relative with PD.
- The patient*s Modified Hoehn and Yahr score is *3 in the ON state and *4 in the OFF state.
- The patient experiences well recognizable and predictable motor fluctuations (at least 1.5 hours of OFF-periods in the awake time, predictable morning OFF episodes included) causing clinically significant disability during the 7-week Screening Period.

Exclusion criteria

- The patient has previously been enrolled in this study.
- The patient takes or has taken disallowed recent or concomitant medication (specified in Appendix II of the CSP) or it is anticipated that the patient will require treatment with at least one of the disallowed concomitant medications during the study. Patients who have taken any non-prescribed systemic or topical medication may participate in the study if, in the opinion of the investigator, the medication will not interfere with the study procedures, study results, or compromise safety.
- The patient is a member of the study personnel or of their immediate families, or is a subordinate (or immediate family member of a subordinate) to any of the study personnel.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-10-2020
Enrollment:	12
Type:	Actual

Ethics review

Approved WMO

Date:	11-12-2019
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO Date:	16-01-2020
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	06-02-2020
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	25-08-2020
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	18-04-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	26-04-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	06-06-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	11-02-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	02-03-2022
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	EUCTR2019-001280-77-NL
CCMO	NL71423.056.19