Interventional, randomized, double-blind, sequential-group, placebo-controlled, single-ascending-oral-dose study investigating the safety, tolerability, pharmacokinetic, and pharmacodynamic properties of Lu AF88434 and open-label crossover study to investigate the intra-individual variability, metabolic profile, and effect of food on Lu AF88434 in healthy young men

Published: 16-07-2019
Last updated: 10-04-2024

This study evaluates the effect of Lu AF88434 on the body and what the body does to Lu AF88434 and the effect of food after swallowing singleoral doses.

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

Summary

ID

NL-OMON48259

Source
ToetsingOnline

Brief title
18144A Lundbeck (190100)

Condition

- Other condition

Synonym
neurological diseases, psychiatric diseases

Health condition

psychiatric and neurological

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: Pharmacodynamics, Pharmocokinetics, 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).

2. Cmax Lu AF88434. Maximum observed plasma concentration.

3. AUC(0-inf) Lu AF88434. Area under the plasma concentration time curve from zero to infinity.

4. CL/F Lu AF88434. Oral clearance for Lu AF88434 in plasma.

5. Total amount of radioactivity excreted.

6. Total recovery of the administered dose (% of dose in urine and faeces).

Secondary outcome

Not applicable.

Study description

Background summary

This study is the first clinical study to be conducted with Lu AF88434. Part A has been designed to investigate the safety, tolerability, and pharmacokinetic and pharmacodynamic properties of Lu AF88434 following single, ascending oral doses administered to healthy young men. Part B has been designed to investigate the intra-individual variability and potential effect of food, as well as investigating mass balance and metabolite profile, using 14C-labelled Lu AF88434. The data obtained in this study will provide the basis for the further clinical development of Lu AF88434.

Study objective

This study evaluates the effect of Lu AF88434 on the body and what the body does to Lu AF88434 and the effect of food after swallowing single oral doses.

Study design

This is the first study in humans with Lu AF88434. It consists of an interventional, randomized, double-blind, sequential-group, placebo-controlled, single-ascending-oral-dose part, followed by an open-label crossover part including a radiolabelled spike.

The study will comprise of two parts: Parts A and B; the dose in Part B will be based on data from Part A.

The study design is presented in
Panel 1 and the scheduled study procedures and assessments are summarized in Panel 2 and Panel 3 for Part A and Part B, respectively (please refer to the protocol for the panels).
Safety and tolerability will be assessed throughout the study. The pharmacokinetic properties of Lu AF88434 will be based on plasma concentration data. For Groups B1 and B2 in Part B, all excreta will be collected in the treatment period the subjects receive the [14C]-labelled spike.

Intervention

Lu AF88434 oral solution
Placebo oral solution

Lu AF99723 ([triazolemethylene-14C]-Lu AF88434) oral solution
Lu AF99722 ([ethoxypyridyl-2,6-14C]-Lu AF88434) oral solution

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

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Healthy young non-smoking men with a body mass index (BMI) * 18.5kg/m2 and *30kg/m2 at the Screening Visit.

Please refer to the protocol for more inclusion criteria.

Exclusion criteria

The subject has any concurrent disorder that may affect the particular target or absorption, distribution, or elimination of the IMP.

Please refer to the protocol for more exclusion criteria.

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):	27-08-2019
Enrollment:	84
Type:	Actual

Ethics review

Approved WMO

Date:	16-07-2019
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO

Date:	17-07-2019
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	24-12-2019
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	03-01-2020
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	10-03-2020
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	09-07-2020
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	EUCTR2018-003561-34-NL
CCMO	NL70222.056.19

Study results

Results posted: 12-01-2022

First publication
20-09-2021