Randomised, double-blind, sequential-group, placebo-controlled, single-ascending oral dose, interventional study, investigating the safety, tolerability, pharmacokinetics, pharmacodynamics and metabolite profile of Lu AF09535 in healthy young men, and an open-label crossover to study intra-subject variability and effects of food

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- to examine the safety and tolerability of the research medication- to examine how the research medication is absorbed, broken down and excreted by the body.

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

Summary

ID

NL-OMON37456

Source
ToetsingOnline

Brief title
14221A

Condition

- Other condition

Synonym
Mental disorder, Mood disorders

Health condition

Mood disorders

Research involving
Human

Sponsors and support

Primary sponsor: Lundbeck
Source(s) of monetary or material Support: Lundbeck

Intervention

Keyword: First in man, healthy men, PK, Single ascending dose

Outcome measures

Primary outcome

Safety and tolerability

Secondary outcome

Pharmacokinetics and pharmacodynamics

Study description

Background summary

The research medication is a new medication developed for the treatment of Fragile X Syndrome.

Study objective

- to examine the safety and tolerability of the research medication
- to examine how the research medication is absorbed, broken down and excreted

by the body.

Study design

This is a randomised, double-blind, sequential-group, placebo-controlled, single-ascending oral dose, interventional study, investigating the safety, tolerability, pharmacokinetics, pharmacodynamics and metabolite profile of Lu AF09535 in healthy young men, and an open-label crossover to study intra-subject variability and effects of food

Intervention

The study will start with a screening. At the screening a physical examination will take place and a few other standard
medical assessments will be performed (ECG, vital signs). Furthermore a blood and urine sample will be taken for
laboratory tests and an alcohol breath test and drug screen will be done.

During the stay in the clinic the subject will receive the study medication and on several time points blood will be taken
and urine will be collected. The subjects will be asked for possible side effects on regular basis. Furthermore several
safety assessments will be done frequently. Also EEG assessment will be done in three cohorts.

Finally, a follow-up visit will take place.

Study burden and risks

Adverse events as seen in animal studies of Lu AF09535 were balance difficulties, increased heart rate, decreased blood pressure, and changes to the measurements of electrical activity in the heart. Events regarding the heart may be felt as palpitations or dizziness. Moreover, changes in laboratory liver- and kidney tests, breathing volumes, and body temperature were seen.

Given the fact that Lu AF09535 is not a registered drug and has not been given to humans before, the doses decided to be administered in this study have been selected based on animal studies. The risks are thus considered to be minimal, but unforeseeable side effects could occur. The subjects health will be monitored carefully and if they experience symptoms, the study physician will ensure that the subjects receive the appropriate care and treatment, if needed.

The blood collection may cause discomfort or bruising. Occasionally, fainting, an infection at the blood sampling site, bleeding and blood clot formation can occur.

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 male

Exclusion criteria

Clinical significant abnormalities at medical research

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):	14-02-2012
Enrollment:	81
Type:	Actual

Ethics review

Approved WMO Date:	02-02-2012
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	02-03-2012
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	13-04-2012
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	EUCTR2011-002925-23-NL
CCMO	NL39565.056.12