Parallel-group, single and multiple dose interventional study investigating the tolerability and pharmacokinetic properties of Lu AF35700 in healthy young men

Published: 12-03-2012
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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	Schizophrenia and other psychotic disorders
Study type	Interventional

Summary

ID

NL-OMON37766

Source
ToetsingOnline

Brief title
14198A

Condition

- Schizophrenia and other psychotic disorders

Synonym
mental disorder

Research involving
Human

Sponsors and support

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

Intervention

Keyword: First in man, Healthy men, Multiple dose, Single dose

Outcome measures

Primary outcome

Safety and tolerability

Secondary outcome

Pharmacokinetics

Study description

Background summary

The research medication is a new medication under development for the treatment of diseases related to the central nervous system (CNS).

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 parallel-group, single and multiple dose interventional study investigating the tolerability and pharmacokinetic properties of the research medication in healthy young men

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. On ambulant visits a blood sample will be taken.

Finally, a follow-up visit will take place.

Study burden and risks

Lu AF35700 has not been previously tested in humans. The compound of Lu AF35700 is expected to be similar to another drug within this class called zicronapine. Clinical studies in healthy subject and in patients show that zicronapine have been well tolerated in humans. Almost all reported adverse effects have been mild-to-moderate in intensity. The most commonly reported side effects for zicronapine are somnolence, sedation, insomnia, anxiety, agitation, weight increase, headache and increased blood enzymes (AST, ALT, creatine phosphokinase), orthostatic hypotension (decrease in blood pressure after change in body positioning), heart trace (ECG) changes. Gastrointestinal side effects such as stomach ache and constipation have also been reported.

Given the fact that Lu AF35700 is not a registered drug and has not been given to humans before, the dose decided to be administered in this study has been selected based on animal studies. The dose has been selected on a level, where risks for side effects are considered to be minimal, but unforeseeable side effects could occur. From animal studies, a risk of some minor extra beats from the heart was identified, however there is included monitoring of the heart during the study.

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:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2012
Enrollment:	29
Type:	Actual

Ethics review

Approved WMO Date:	12-03-2012
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	30-03-2012
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	EUCTR2011-002671-41-NL
CCMO	NL40077.056.12