An open-label, one-sequence crossover interaction study investigating the effect of multiple doses of Lu AE58054 on cytochrome P450 3A4 and 2D6 activity measured by midazolam and dextromethorphan pharmacokinetics in healthy young men

Published: 03-09-2010
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To study how the registered medicine Midazolam is absorbed, broken-down and excreted by the body after or without administration of multiple doses of the test compound.To study how the registered medicine Dextromethorphan is absorbed, broken-down...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Mental impairment disorders
Study type	Interventional

Summary

ID

NL-OMON34119

Source
ToetsingOnline

Brief title
12743A

Condition

- Mental impairment disorders
- Schizophrenia and other psychotic disorders

Synonym

Cognitive Impairment Associated with Schizophrenia and Alzheimer's disease

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Healthy young men, Interaction, One-sequence crossover, Open-label

Outcome measures

Primary outcome

To investigate the effect of multiple doses research medication on PK

parameters for Midazolam and Dextromethorphan..

Secondary outcome

To examine the safety and tolerability of the research medication

Study description

Background summary

The research medication is a new medication developed for the treatment of cognitive impairment associated with Schizophrenia and Alzheimer's disease

Study objective

To study how the registered medicine Midazolam is absorbed, broken-down and excreted by the body after or without administration of multiple doses of the test compound.

To study how the registered medicine Dextromethorphan is absorbed, broken-down and excreted by the body after or without administration of multiple doses of the test compound.

To investigate the safety and tolerability of the test compound after multiple dosing alone or in combination with single dosing of the registered medicines

Midazolam and Dextromethorphan.

Study design

An open-label, one-sequence crossover interaction study investigating the effect of multiple doses of research medication measured by midazolam and dextromethorphan pharmacokinetics

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 labortaory tests. An alcohol breath test and drug screen will also be performed.

During the stay in the clinic, the subject will receive the study medication (including Midazolam and Dextromethorphan) and on several time-points blood will be taken. The subjects will be asked for possible side effects on a regular basis. Furthermore ECG's and vitals signs assessments will be performed and checked regularly

Finally a follow-up visit will take place

Study burden and risks

Possible side effects of the research medication may include dizziness, headache and a numb tongue, gastrointestinal disorders (dry mouth and vomiting) and nervous system disorders (headache, dizziness, sedation, anxiety)

Dextromethorphan and Midazolam are drugs which are prescribed and used clinically for long time.

Possible side effects of Dextromethorphan may include stomach upset, nausea, drowsiness, and dizziness.

Possible side effects of Midazolam may include drowsiness, cognitive impairment, sedation, confusion, headache, dizziness and double vision.

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 during medical research

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):	13-09-2010
Enrollment:	22
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Dextromethorphan
Generic name:	Dexofan
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Midazolam
Generic name:	Dormicum
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	03-09-2010
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	10-09-2010
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	EUCTR2008-005868-14-NL
CCMO	NL33734.056.10