Randomised, double-blind, placebo-controlled single ascending dose study investigating the safety, tolerability, pharmacokinetic and pharmacodynamic properties of the research medication in healthy young and elderly men, and open-label three-period crossover food interaction study of the research medication in healthy elderly men

Published: 19-02-2010
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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	-
Status	Completed
Health condition type	Movement disorders (incl parkinsonism)
Study type	Interventional

Summary

ID

NL-OMON36711

Source
ToetsingOnline

Brief title
13065A

Condition

- Movement disorders (incl parkinsonism)

Synonym
Parkinson□s disease

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Double-blind, healthy men, PK, Single dose study

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 Parkinson*s disease.

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, placebo-controlled single ascending dose study.

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.

Finally, a follow-up visit will take place.

Study burden and risks

Possible side effects may include headache, nausea, vomiting, increased heart rate and lowered blood pressure which could lead to dizziness (in particular with fast standing up).

The doses are chosen from research in lab animals. The risks with these doses is likely to be minimal, but as with all clinical drug studies, unforeseeable adverse reactions could occur. In order to keep the risks as low as possible, subjects will be monitored carefully during the whole study.

Contacts

Public
Lundbeck

Ottiliavej 9
2500 Copenhagen-Valby
DK
Scientific
Lundbeck

Ottiliavej 9
2500 Copenhagen-Valby
DK

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:	Completed
Start date (anticipated):	08-03-2010
Enrollment:	171
Type:	Actual

Ethics review

Approved WMO Date:	10-11-2011
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	EUCTR2009-013125-42-NL
CCMO	NL31521.056.10