

# 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.

<b>Ethical review</b>	-
<b>Status</b>	Completed
<b>Health condition type</b>	Movement disorders (incl parkinsonism)
<b>Study type</b>	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**

2 - Randomised, double-blind, placebo-controlled single ascending dose study investi ... 25-05-2025

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**

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### **Scientific**

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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:	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