A combined Single and Multiple Rising Dose Study to Investigate the Safety, Tolerability and Pharmacokinetics of SCH900062 in Healthy Adult Volunteers

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The purpose of this trial is to research how the new medication SCH 900062 after single and multiple dosing is absorbed, broken-down and excreted by the body when in the fasting state and after eating a high fat meal. This trial is necessary for the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cognitive and attention disorders and disturbances
Study type	Observational invasive

Summary

ID

NL-OMON32905

Source
ToetsingOnline

Brief title
SCH900062 FIH study

Condition

- Cognitive and attention disorders and disturbances

Synonym
Alzheimer Disease, cognitive dysfunction

Research involving
Human

Sponsors and support

Primary sponsor: Schering-Plough

Source(s) of monetary or material Support: Schering Plough

Intervention

Keyword: FIM, MAD, SAD

Outcome measures

Primary outcome

Safety and tolerability

Secondary outcome

Pharmacokinetics, bioavailability

Study description

Background summary

SCH 900062 is not registered as a medicine. SCH 900062 is a drug that is being developed for the treatment of patients suffering from cognitive impairment.

Cognition is the name given to brain activities involving the processes of learning, perception, remembering, thinking, interpreting, believing and problem solving. In cases of cognitive impairment, these processes are disrupted which can result in a reduced memory, attention span and flexibility and can cause various conditions. These conditions include Alzheimer*s and schizophrenia.

Study objective

The purpose of this trial is to research how the new medication SCH 900062 after single and multiple dosing is absorbed, broken-down and excreted by the body when in the fasting state and after eating a high fat meal.

This trial is necessary for the further development of SCH 900062.

Study design

This trial is a triple-blind, randomized study with a placebo control group.

In part I 18 healthy male/female test subjects will participate in the trial and will be split into two groups of 9 people. For both groups the trial

excists of 4 periods of 4 days wherein a single dose will be given.

In part II 36 healthy male/female test subjects will participate in the trial and will be split into three groups of 12 people. For all groups the trial excists of 1 periods of 16 days wherein a multiple dose will be given.

Study burden and risks

The test medication has not previously been tested in humans. Results from animal testing have shown that with high doses, locomotion impairment can occur, mostly observed as trembling of the limbs and an unsteady pace. It is possible that this may also occur in this trial.

The dose levels are selected on the basis of research results in animals and humans. The risks to health at these dose levels are limited but the subjects may experience one of the above mentioned side-effects or other symptoms not previously reported. The subject's health will be closely monitored during the trial to minimize these risks.

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

Males and females
Between 30-60 years of age

Exclusion criteria

Clinical significant abnormalities for medical examination

Study design

Design

Study type:	Observational invasive
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):	30-12-2009
Enrollment:	54
Type:	Actual

Ethics review

Approved WMO Date:	15-12-2009
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	22-12-2009
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	EUCTR2009-017198-40-NL
CCMO	NL30564.056.09