A double-blind, randomized, placebo-controlled study to assess the safety, tolerability, pharmacokinetics and pharmacodynamics of single ascending oral doses of ASP2905 in healthy young males, including an open-label two-period randomized crossover study to compare the pharmacokinetics under fasted and fed conditions

Published: 01-04-2008
Last updated: 07-05-2024

nvt

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON32022

Source
ToetsingOnline

Brief title
ASP2905 SAD/food effect study

Condition

- Other condition

Synonym
Alzheimer's Disease and schizophreny

Health condition

ziekte van Alzheimer, schizofrenie

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Alzheimer, ASP2905, Food effect, SAD

Outcome measures

Primary outcome

nvt

Secondary outcome

nvt

Study description

Background summary

nvt

Study objective

nvt

Study design

nvt

Intervention

nvt

Study burden and risks

nvt

Contacts

Public
Astellas Pharma

Elisabethhof 19
2350 AC Leiderdorp
Nederland
Scientific
Astellas Pharma

Elisabethhof 19
2350 AC Leiderdorp
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Healthy young male subject, aged 18-50 years inclusive.

Exclusion criteria

current clinically significant diseases or conditions or any clinical significant diseases or conditions in medical history.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-05-2008
Enrollment:	68
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	nvt
Generic name:	placebo

Ethics review

Approved WMO

Date:	01-04-2008
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek

	(Assen)
Approved WMO Date:	08-04-2008
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	28-08-2008
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	EUCTR2007-006108-39-NL
CCMO	NL22674.056.08