A PHASE 1, SINGLE ASCENDING DOSE, MULTIPLE ASCENDING DOSE AND SINGLE DOSE FOOD EFFECT STUDY TO INVESTIGATE THE SAFETY, TOLERABILITY AND PHARMACOKINETICS OF LND101001 IN HEALTHY MALE AND FEMALE SUBJECTS

Published: 19-10-2012
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Primary objective: to assess the safety and tolerability and pharmacokinetics of LND101001 administered as single and multiple doses; Secondary: to assess the effect of food and gender on pharmacokinetics.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Structural brain disorders
Study type	Interventional

Summary

ID

NL-OMON37192

Source
ToetsingOnline

Brief title
LND101001 single and multiple ascending dose study

Condition

- Structural brain disorders

Synonym
Alzheimer's disease; dementia

Research involving

Human

Sponsors and support

Primary sponsor: Lupin Ltd
Source(s) of monetary or material Support: Farmaceutische industrie

Intervention

Keyword: alpha7-Nicotinic acetylcholine receptors modulation, Alzheimer's disease, first in human, LND101001

Outcome measures

Primary outcome

Criteria for evaluation

Pharmacokinetics: concentration of LND101001 in plasma after single and

multiple ascending doses, PK parameters

Safety: AEs, vital signs, 12-lead ECG, telemetry, clinical laboratory, physical

examination

Statistical Methods:

PK parameters : analysis of variance on Cmax and AUC, other parameters

descriptive statistics

Safety parameters : descriptive statistics

Secondary outcome

similar primary parameters; data following administration of LND101001 under

fasted and fed conditions will be compared and differences between males and

females

Study description

Background summary

LND101001 is a new investigational compound (positive allosteric modulator of the alpha 7 nicotinic acetylcholine receptor) that may be used in the treatment of Alzheimer's disease. This is a first in human study.

Study objective

Primary objective: to assess the safety and tolerability and pharmacokinetics of LND101001 administered as single and multiple doses; Secondary: to assess the effect of food and gender on pharmacokinetics.

Study design

Single ascending doses: 5 groups of 8 volunteers, one group of 10 volunteers (6 LND101001; 2 placebo; 8 : 2 in the group that consists of 10 volunteers); group 2 (FE) will participate in 2 periods and receive the same dose in each period, under fasted conditions in one period, under fed conditions in the other period (food-effect part) (6 LND101001; 2 placebo)
Multiple ascending doses: 3 group of 8 volunteers (6 LND101001; 2 placebo)

Intervention

single ascending doses: single administration of a capsule, doses 7.5 - 400 mg (food-effect: 2 drug administrations)
multiple ascending doses: one capsule daily during 14 days; dose levels to be determined based on findings in the single ascending dose part of the study.

Study burden and risks

- possible side-effects as decribed under E9
- venipunctures and blood draws via cannula
- pre-screening and follow-up visit
- admission in clinic
- several ambulant visits
- study activities: a.o: physical examinations (SAD 3x, MAD 4x), telemetric monitoring, ECG's, vital signs

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

- SAD: healthy male and female subjects, MAD: healthy male subjects
- 18-65 yrs, inclusive
- BMI: 18.0-30.0 kg/m2, inclusive
- non-smoking

Exclusion criteria

Suffering from hepatitis B, hepatitis C, cancer or HIV/AIDS. In case of participation in another drug study within 90 days before the start of this study or being a blood donor within 60 days from the start of the study. In case of donating more than 1.5 liters of blood in the 10 months prior the start of this study.

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:	Recruitment stopped
Start date (anticipated):	01-11-2012
Enrollment:	74
Type:	Actual

Ethics review

Approved WMO

Date:	19-10-2012
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO

Date:	29-10-2012
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	EUCTR2012-004141-32-NL
CCMO	NL42152.056.12