A first-in-human, randomized, double-blind, placebo-controlled, single ascending dose and multiple ascending dose study to investigate the safety, tolerablility, pharmacokinetics (including food and gender effect), and pharmacodynamics of LNP1955 in healthy subjects.

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

Summary

ID

NL-OMON42416

Source
ToetsingOnline

Brief title
LNP1955 Single and multiple ascending dose study.

Condition

- Autoimmune disorders

Synonym
Inflammatory disease conditions, rheumatoid arthritis.

Research involving
Human

Sponsors and support

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

Intervention

Keyword: inflammatory disease, LNP1955, rheumatoid arthritis

Outcome measures

Primary outcome

To assess the safety and tolerability of single and multiple ascending oral

doses of LNP1955 in healthy subjects.

Secondary outcome

To assess the pharmacokinetics (PK) of single and multiple ascending oral doses

of LNP1955 in healthy subjects.

Study description

Background summary

LNP1955 is a new investigational compound that may eventually be used for the treatment of inflammatory disease conditions such as rheumatoid arthritis. Inflammation is an immune reaction of the body to presumed foreign substances. In case of an auto immune response the reaction is to cells of the human body itself. Inflammation is characterized by increased blood supply and activation of defense mechanisms. It produces redness, swelling, heat and pain. The compound that will be researched in this study, LNP1955, is expected to block a protein (CRAC channel) that is involved in abnormal immune responses seen in this type of conditions. This is the first time that this compound is being given to humans.

Study objective

The purpose of the study is to investigate to what extent LNP1955 is tolerated and safe.
It will also be investigated how quickly and to what extent LNP1955 is absorbed and eliminated from the body (this is called pharmacokinetics). Further, the effect of food and gender on the pharmacokinetics will be investigated. In addition, the effect of the compound on certain proteins in your blood will be investigated (this is called pharmacodynamics).

Study design

SAD:
The actual study will consist of 1 period during which the subjects will stay in the clinical research center in Groningen for 6 days (5 nights).
The subjects are expected at the clinical research center at 14:00 h in the afternoon prior to the day of first administration of study compound. The subjects will be required not to have consumed any food or drinks during the 4 hours prior to arrival in the clinical research center (with the exception of water).
The subjects will leave the clinical research center on Day 5. (Day 1 is the day of administration of study compound). The post-study screening will be scheduled on Day 12 ± 2. The subject*s participation to the entire study, from pre-study screening until the post study screening, will be maximally 5 weeks.

FE:
The actual study will consist of 2 periods. In each period the subjects will stay in the clinical research center in Groningen for 6 days (5 nights).
In each period, the subjects are expected at the clinical research center at 14:00 h in the afternoon prior to the day of first administration of study compound.
The subjects will be required not to have consumed any food or drinks during the 4 hours prior to arrival in the clinical research center (with the exception of water).
The subjects will leave the clinical research center on Day 5 of each period. (Day 1 is the day of administration of study compound). The post-study screening will be scheduled on Day 12 (± 2 days) of Period 2.
The time interval between study compound administration in the different periods is at least 2 weeks.
The subject*s participation to the entire study, from pre-study screening until the post study screening, will be maximally 7-8 weeks.

MAD:
The actual study will consist of 1 period during which the subject will stay in

the clinical research center in Groningen for 19 days (18 nights).
The subjects are expected at the clinical research center at 14:00 h in the afternoon prior to the day of first administration of study compound.
The subjects will be required not to have consumed any food or drinks during the 4 hours prior to arrival in the clinical research center (with the exception of water).
The subjects will leave the clinical research center on Day 18. (Day 1 is the first day of administration of study compound). The post-study screening will be scheduled on Day 25 (± 2 days). The subject*s participation to the entire study, from pre-study screening until the post study screening, will be maximally 7 weeks.

Intervention

Single ascending dose, multiple ascending dose, gender and food effect.

Study burden and risks

All potential drugs cause adverse events; the extent to which this occurs differs. As LNP1955 will be administered to humans for the first time in this study, adverse effects of LNP1955 in humans have not been reported to date. However, based on the findings observed in animal studies, the calcium levels in the blood may show an increase. Generally such an increase in calcium occurs without any symptoms. However if the increase is significant, the symptoms related to increase in calcium like nausea, vomiting, headache, increased thirst, lethargy, weakness and inflammation might be observed. Single doses of LNP1955 which were tested at different doses up to 60mg/kg/day were well tolerated in rats.

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

Healthy volunteers
18-65 yrs, inclusive
BMI: 18.0-32.0 kg/m2, inclusive

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:	Other
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-05-2015
Enrollment:	66
Type:	Actual

Ethics review

Approved WMO Date:	06-05-2015
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	26-05-2015
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	EUCTR2015-001493-18-NL
CCMO	NL53335.056.15