Assessment of safety, tolerability and pharmacokinetics of single and multiple ascending oral doses of GLPG2451 and of the combination of GLPG2451 and GLPG2222 in healthy female subjects.

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

Summary

ID

NL-OMON42997

Source
ToetsingOnline

Brief title
GLPG2451 SAD/MAD Study.

Condition

- Other condition

Synonym
cystic fibrosis

Health condition

Taaislijmziekte, cystische fibrose

Research involving
Human

Sponsors and support

Primary sponsor: Galapagos SASU
Source(s) of monetary or material Support: Farmaceutische Industrie.

Intervention

Keyword: cystic fibrosis, GLPG2222, GLPG2451

Outcome measures

Primary outcome

To evaluate the safety and tolerability of single ascending oral doses (SAD) of GLPG2451 given to healthy female subjects, compared to placebo.

To evaluate the safety and tolerability of multiple ascending oral doses (MAD) of GLPG2451 given to healthy female subjects daily for 14 days, compared to placebo.

To evaluate the safety and tolerability of two combined doses of GLPG2451 and GLPG2222 given to healthy female subjects for 14 days, compared to placebo.

Secondary outcome

To characterize the PK of GLPG2451 after single and multiple oral administrations.

To characterize the PK of GLPG2451 and GLPG2222 when given concomitantly.

To explore the potential of CYP3A4 interaction by repeated dosing with GLPG2451.

Study description

Background summary

GLPG2451 is a new investigational compound that may eventually be used for the treatment of cystic fibrosis (CF). CF is a genetic disorder that causes the body to produce unusually thick mucus. The thick mucus results in malfunction of organs like the lungs, pancreas and liver.
In the human body, the cystic fibrosis transmembrane conductance regulator (CFTR; this is a protein that can be found on the membrane of cells) plays an important role in the transport of salt and water in and out of cells. In CF there are mutations in the gene (DNA) that is responsible for the production of CFTR and because of these mutations CFTR does not work correctly or it is not produced sufficiently. As a result, the transport of salt and water in and out of cells is disturbed and mucus will become unusually thick. GLPG2451 is thought to improve CFTR functioning by repairing consequences of CFTR mutations. GLPG2451 is not registered as a drug and has not been given to humans before.

Study objective

This study will be performed in about 56 healthy female volunteers. The study will be performed in 3 parts, Parts 1, 2 and 3.
In Part 2, multiple doses of GLPG2451 or placebo (same formulation but without the active ingredient GLPG2451) will be administered and about 3 dose levels of GLPG2451 will be investigated in Part 2. The purpose of Part 2 is to investigate how safe GLPG2451 is and how wellGLPG2451 is tolerated. Part 2 will also investigate how quickly and to what extent GLPG2451 is absorbed into, distributed in, and eliminated from the body (this is called pharmacokinetics). Part 2 will be performed in about 3 dose groups (Cohorts C, D and E) and each dose group will consist of 8 healthy female volunteers. Part 2 will be performed in about 24 healthy female volunteers.

Study design

The actual study will consist of 1 treatment period during which the volunteers will stay in the clinical research center in Groningen for 17 days (16 nights): from the afternoon of Day -1 (1 day before the first administration of the study compound) to the morning of Day 16.
The post-study visit will take place 14 days after the last administration of the study compound on Day 14. The appointment for the post-study visit will be made with you during the study. The participation to the entire study, from the screening until the post-study visit, will be approximately 7 weeks.

Intervention

Cohort C Day 1 to 14 GLPG2451 15 mg (administered as 15 mg once daily or 7.5 mg

twice daily) or placebo
Cohort D Day 1 to 14 GLPG2451 45 mg (administered as 45 mg once daily or 22.5 mg twice daily) or placebo
Cohort E Day 1 to 14 GLPG2451 100 mg (administered as 100 mg once daily or 50 mg twice daily) or placebo

Study burden and risks

Procedures: pain, minor bleeding, bruising, possible infection.

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 sterilized women or healthy postmenopausal women
18 - 65 years, inclusive
BMI 18.0 - 30.0 kg/m2
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):	01-06-2016
Enrollment:	56
Type:	Actual

Ethics review

Approved WMO

Date:	17-05-2016
Application type:	First submission

Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	24-05-2016
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	EUCTR2016-000733-47-NL
CCMO	NL57798.056.16