A Phase I, open-label, randomized, two-way crossover study to investigate the effects of morning versus evening repeated dosing on the pharmacokinetics of the combination of GLPG3067, GLPG2222 and GLPG2737 in healthy female subjects.

Published: 14-12-2017
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- To evaluate the pharmacokinetic (PK) profile of the combination of GLPG3067, GLPG2222, and GLPG2737 following repeated morning versus evening doses given to healthy female subjects - To evaluate the safety and tolerability of the combination of...

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

Summary

ID

NL-OMON44378

Source
ToetsingOnline

Brief title
Study to investigate the combination of GLPG3067,GLPG2222 and GLPG2737

Condition

- Other condition

Synonym
Cystic Fibrosis, Mucoviscidosis

Health condition

Cystische Fibrose

Research involving
Human

Sponsors and support

Primary sponsor: Galapagos N.V.
Source(s) of monetary or material Support: Farmaceutische industrie

Intervention

Keyword: cystic fibrosis, GLPG2222 and GLPG2737, GLPG3067

Outcome measures

Primary outcome

PK parameters (including AUCtau, Cmax, and C24h) of GLPG3067, GLPG2222, and

GLPG2737 in plasma following combined administration of GLPG3067, GLPG2222, and

GLPG2737.

Secondary outcome

Determine safety and tolerability of the combination of GLPG3067, GLPG2222, and

GLPG2737 in healthy adult female subjects, assessed by the number of subjects

with AEs.

Study description

Background summary

Cystic fibrosis (CF) is an autosomal recessive genetic disease caused by mutations in the gene encoding for the cystic fibrosis transmembrane conductance regulator (CFTR) protein. CFTR dysfunction results in viscid secretions that are difficult to clear, affecting most exocrine glands, notably the pancreas, intestine, liver, and bile duct. However, most morbidity and mortality results from dehydration of the airway surface liquid and impaired

airway mucociliary clearance, which leads to cycles of bacterial infection, chronic inflammation, bronchiectasis and progressive decline in pulmonary function. GLPG has set up a development program that aims to effectively treat CF by developing a combination therapy composed of multiple CFTR modulators with complementary mode of action.

For further information, reference is made to the introduction of the protocol.

Study objective

- To evaluate the pharmacokinetic (PK) profile of the combination of GLPG3067, GLPG2222, and GLPG2737 following repeated morning versus evening doses given to healthy female subjects
- To evaluate the safety and tolerability of the combination of GLPG3067, GLPG2222, and GLPG2737 given to healthy female subjects

Study design

This study will be performed in up to 10 healthy volunteers.

The study will consist of 2 treatment periods during which the volunteer will receive a combination of GLPG3067, GLPG2222 and GLPG2737 as multiple doses for 7 days in the morning in one treatment period and as multiple doses for 7 days in the evening in the other treatment period. GLPG3067, GLPG2222 and GLPG2737 will be given as oral tablets (GLPG3067 and GLPG2222) or oral capsules (GLPG2737) with 240 mL of water.

For further information, reference is made to the protocol.

Intervention

n.a.

Study burden and risks

There is no direct benefit for the subjects from taking part in the study. The results of the study will provide valuable information for future research. Not all side effects of new compounds, such as GLPG3067, GLPG2222 and GPLG2737 are known. Unexpected side effects might occur.

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

- Female subject between 18-70 years of age, inclusive, on the date of signing the informed consent form (ICF).
- Being of non-childbearing potential, defined as surgically sterile (hysterectomy, bilateral salpingectomy and bilateral oophorectomy), or post-menopausal (at least 12 consecutive months without menstruation, without an alternative medical cause [including hormone replacement therapy]). In addition, a determination of follicle stimulating hormone (FSH) must be performed with FSH >35 mIU/mL to further confirm postmenopausal status without menstruation for >12 months. Subjects must have a negative serum pregnancy test. For surgical sterilization, documented confirmation will be requested.
- Having a body mass index (BMI) between 18-30 kg/m2, inclusive.
- Judged by the investigator to be in good health based upon the results of a medical history, physical examination, vital signs, 12-lead triplicate ECG, and clinical safety laboratory tests prior to the initial study drug administration. Clinical safety laboratory test results must be within the laboratory reference ranges for women, or test results that are outside the reference ranges for women need to be considered non-clinically significant in the opinion of the investigator.;Reference is made to the protocol for a complete overview of the inclusion criteria.

Exclusion criteria

- Presence or having sequelae of gastrointestinal, liver, kidney, or other conditions known to interfere with the absorption, distribution, metabolism, or excretion of drugs.
- Creatinine clearance <=80 mL/min using the Cockcroft-Gault formula for subjects aged <=50 years, or creatinine clearance <=70 mL/min using the Cockcroft-Gault formula for subjects aged >50 years. A 24-hour urine collection to determine the actual value may be performed to confirm creatinine clearance if required.
- Treatment with any drug known to have a well-defined potential for toxicity to a major organ in the last 3 months or 5 times the half-life of the drug (whichever is longer) before the initial study drug administration.
- Participation in a drug, drug and device delivery system or combination, or biological investigational research study within 8 weeks or 5 times the half-life of the investigational drug, if the half-life is known (whichever is longer) prior to initial study drug administration.
;Reference is made to the protocol for a complete overview of the exclusion criteria.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-12-2017
Enrollment:	10
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Not applicable
Generic name:	GLPG2222

Product type:	Medicine
Brand name:	Not applicable
Generic name:	GLPG2737

Ethics review

Approved WMO Date:	14-12-2017
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	28-12-2017
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	22-03-2018
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	EUCTR2017-004507-44-NL
CCMO	NL64055.056.17