A Phase I, open-label, randomized, single-dose, two-way crossover study to compare the relative bioavailability of GLPG2737 given as a capsule formulation and an oral suspension

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- To assess the relative bioavailability of GLPG2737 administered as a single capsule compared to a single oral suspension in the fed state.- To assess the safety and tolerability in healthy subjects of GLPG2737 administered as a capsule and as an...

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

Summary

ID

NL-OMON45861

Source
ToetsingOnline

Brief title
Pharmacokinetics of GLPG2737 given as a capsule and an oral suspension

Condition

- Other condition
- Congenital and hereditary disorders NEC

Synonym
Cystic fibrosis; mucoviscidosis; thick mucus disease

Health condition

Cystic fibrosis

Research involving
Human

Sponsors and support

Primary sponsor: Galapagos NV
Source(s) of monetary or material Support: Galapagos NV

Intervention

Keyword: Cystic fibrosis, GLPG2737, Pharmacokinetics

Outcome measures

Primary outcome

- Determine PK parameters of GLPG2737 in plasma after administration of a

single dose of a suspension and of a capsule formulation in healthy subjects.

- Determine safety and tolerability of GLPG2737 in healthy male subjects, as

assessed by the number of subjects with adverse events (AEs).

Secondary outcome

Not applicable

Study description

Background summary

Cystic fibrosis (CF) is caused by mutations in the gene encoding for the cystic fibrosis transmembrane conductance regulator (CFTR) protein, a cyclic adenosine monophosphate (cAMP)-regulated anion channel expressed primarily at the apical plasma membrane of secretory epithelia. Nearly 2000 mutations in the CFTR gene (CFTR) have been identified, which are grouped into six classes (class I-VI). The F508del mutation is by far the most common CFTR mutation globally, especially in the Caucasian population. Approximately 90% of CF patients in the United States and Europe have at least one copy of this mutation on one allele, with almost half of them being F508del homozygous (i.e. the mutation is present on both alleles). The F508del mutation impairs CFTR folding, trafficking towards the plasma membrane, has reduced plasma membrane stability, and reduced chloride gating. Thus, patients with the F508del mutation have very little to

no CFTR protein at the apical membrane. The absence of CFTR function 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. There is currently an unmet medical need for adequate therapeutic approaches to treat CF patients with the F508del mutation.

Study objective

- To assess the relative bioavailability of GLPG2737 administered as a single capsule compared to a single oral suspension in the fed state.
- To assess the safety and tolerability in healthy subjects of GLPG2737 administered as a capsule and as an oral suspension in healthy male subjects.

Study design

This is a Phase I, open-label, randomized, single-dose, two-way crossover study to explore the relative bioavailability of GLPG2737 given as a capsule formulation compared to an oral suspension in the fed state.

Intervention

a single dose of GLPG2737 on two occasions

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 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

- Male between 18-50 years of age, inclusive, on the date of signing the Informed Consent Form (ICF).
- 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 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 males or test results that are outside the reference ranges for males need to be considered non clinically significant in the opinion of the investigator. One retest is allowed if deemed appropriate by the investigator without asking permission from the sponsor.
- Discontinuation of all medications (including over-the-counter and/or prescription medication, dietary supplements, nutraceuticals, vitamins and/or herbal supplements) except occasional paracetamol (maximum dose of 2 g/day and maximum of 10 g/2 weeks) least 2 weeks prior to the first study drug administration.;Reference is made to the protocol for a complete overview of the inclusion criteria.

Exclusion criteria

* History of or a current immunosuppressive condition (e.g., human immunodeficiency virus [HIV] infection type 1 and 2).
* Clinically significant illness in the 3 months before screening.
* Presence or having sequelae of gastrointestinal, liver, kidney (creatinine clearance [CLCR] * 80 mL/min using the Cockcroft-Gault formula: if calculated result * 80 mL/min, a 24 hour

urine collection to determine actual value can be done) or other conditions known to interfere with the absorption, distribution, metabolism, or excretion of drugs.
* Treatment with any drug known to have a well-defined potential for toxicity to a major organ within the last 3 months or 5-half-lives of the drug (whichever is longer) before the initial drug administration.
* Participation in a drug, drug and device delivery system or combination or biologic 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 screening.;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):	10-05-2017
Enrollment:	12
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO

Date:	25-04-2017

Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	08-05-2017
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	EUCTR2016-004984-38-NL
CCMO	NL61566.056.17