A controlled in vitro hypersensitivity assessment in subjects previously treated whit the combination of GLPG3067 and GLPG2222, or the combination of GLPG3067, GLPG222 and GLPG2737 using Lymphocyte Transformation Test.

Published: 25-06-2018
Last updated: 11-04-2024

During the previous study GLP973EC-179731/GLPG3067-CL-108 in which GLPG3067, GLPG2222 and GLPG2737 were administered, some volunteers developed a hypersensitivity skin reaction (rash). As this is an important event for the further development of the...

Ethical review	Approved WMO
Status	Pending
Health condition type	Epidermal and dermal conditions
Study type	Observational invasive

Summary

ID

NL-OMON45940

Source
ToetsingOnline

Brief title
Study to investigate hypersensitivity with a LTT test.

Condition

- Epidermal and dermal conditions

Synonym
Skin reaction (e.g. rash)

Research involving
Human

Sponsors and support

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

Intervention

Keyword: cystic fybrosis, GLPG2222 and GLPG2737, GLPG3067, hypersensitivity, LTT test

Outcome measures

Primary outcome

For this follow-up study, blood will be collected and this blood will be used

for a so called lymphocyte transformation test (LTT). The LTT is a useful test

for the diagnosis of drug hypersensitivity. The LTT will be done in order to

better understand the cause of these hypersensitivity skin reactions.

Secondary outcome

N/A

Study description

Background summary

GLPG3067, GLPG2222 and GLPG2737 are new compounds 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.

Study objective

During the previous study GLP973EC-179731/GLPG3067-CL-108 in which GLPG3067, GLPG2222 and GLPG2737 were administered, some volunteers developed a hypersensitivity skin reaction (rash). As this is an important event for the further development of the study compounds, the Sponsor would like to investigate this further in a follow-up study. In this follow up study,

volunteers who developed a skin reaction will be included and . Tto be able to fully understand the processes that lead to the skin reaction, also volunteers that have not suffered from a skin reaction will be included.

Study design

The volunteer will be contacted by phone and will be invited to participate in this follow-up study. This study consists of 1 visit only. Firstly, the responsible doctor or a member of the study staff will discuss the study and the requirements for participation in this study with you.

The volunteer can participate in this study because you have participated in study GLP973EC 179731/GLPG3067-CL-108 before. The volunteer will however be excluded from participation in this study if the volunteer has received another study compound in the meantime. It is therefore important that the volunteer is completely truthful with the responsible doctor and study staff about this.

After consenting to participate in the study (by signing and dating this document), the following items will be reviewed for the period between the end of study GLP973EC 179731/GLPG3067 CL-108 and the current visit:
- use of medication
- participation in another clinical study with a study compound

After that, 12 tubes of 8 milliliters of blood (96 milliliters in total) will be taken. These blood samples will be used for in vitro testing (*test-tube experiments*) of hypersensitivity reactions to one of the study compounds that were given in the GLP973EC 179731/GLPG3067 CL-108 study. No other assessments will be done.

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.

Contacts

Public
Galapagos N.V.

Generaal de Wittelaan L11 A3

Mechelen 2800
BE
Scientific
Galapagos N.V.

Generaal de Wittelaan L11 A3
Mechelen 2800
BE

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- trial subjects: subjects who participated in Part 4 or Part 5 of the GLPG3067 -CL -101 or the GLPG3067-CL-108 clinical trial and developed skin reactions suspected as drug hypersensitivity, OR
-control subjects: subjects who participated in Part 4 or Part 5 of the GLPG3067- CL- 101 or the GLPG3067-CL-108 clinical trial and did not develop any skin reaction or drug hypersensitivity signs.;- Able and willing to comply with the protocol requirements and to sign the ICF as approved by the Independent Ethics Committee (IEC), before any study-related procedures are performed.

Exclusion criteria

- Any condition or circumstances that in the opinion of the investigator may make a subject unlikely or unable to complete the study or comply with study procedures and requirements.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	11-06-2018
Enrollment:	2
Type:	Anticipated

Ethics review

Approved WMO

Date:	25-06-2018
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
CCMO	NL65952.056.18