A phase I study to investigate the pharmacokinetics, safety and tolerability of four different dosing regimens of GRC 17536 in healthy male volunteers using tablet formulation.

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

Summary

ID

NL-OMON42613

Source
ToetsingOnline

Brief title
GRC 17536 multiple dose study in healthy volunteers.

Condition

- Other condition

Synonym
Pain and respiratory conditions

Health condition

Pijn en luchtwegaandoeningen

Research involving
Human

Sponsors and support

Primary sponsor: Glenmark Pharmaceuticals SA
Source(s) of monetary or material Support: Farmaceutische Industrie.

Intervention

Keyword: GRC 17536, Pain, Respiratory conditions

Outcome measures

Primary outcome

To assess the pharmacokinetics of GRC 17536 following multiple oral administration of tablet formulations at four different dose levels: (a) two tablets of 90 mg GRC 17536 twice daily (i.e., 360 mg daily dose), (b) three tablets of 90 mg GRC 17536 twice daily (i.e., 540 mg daily dose), (c) four tablets of 90 mg GRC 17536 twice daily (i.e., 720 mg daily dose), and (d) three tablets of 45 mg twice daily (i.e., 270 mg daily dose) administered in normal healthy adult male subjects.

Secondary outcome

To evaluate the safety and tolerability of GRC 17536 in normal healthy adult male subjects following multiple oral administration of the tablet formulations.

Study description

Background summary

GRC 17536 is a new investigational compound that may eventually be used for the treatment of acute and chronic pain conditions as well as respiratory

conditions such as asthma, chronic obstructive pulmonary disease (COPD), cough, and related disorders. GRC 17536 is a molecule that specifically recognizes, binds and blocks the function of the TRPA1 receptor. A receptor is a protein on the surface of a cell to which a signaling molecule can bind, causing a change in the activity of the cell. TRPA1 receptors are mainly present in neurons that sense pain and play an important role in pain signaling and they are present in nerves in the airways where it is thought to play an important role in respiratory inflammation. The sensation of pain and inflammatory reactions can be reduced by blocking the TRPA1 receptor.

GRC 17536 is not registered as a drug but has been given to humans before in 4 previous clinical studies .

Study objective

n 2 out of 3 previous clinical studies a granule formulation (powder) of GRC 17536 was investigated and in 1 study various tablet formulations of GRC 17536 were investigated. The results from these studies showed that GRC 17536 is absorbed better into the blood when administered as a tablet compared to administration as a granule formulation. Therefore, the tablet formulations have been selected for further investigation in this study.

The purpose of the study is to investigate how quickly and to what extent multiple doses of the tablet formulations of GRC 17536 are absorbed and eliminated from the body (this is called pharmacokinetics). From the obtained data an optimal dose level for future studies in patients will be selected.
It will also be investigated to what extent multiple doses of the tablet formulations of GRC 17536 are tolerated.

This study will be performed in 28 healthy male volunteers.

Study design

The actual study will consist of 1 period during which the volunteers will stay in the clinical research center in Groningen for 29 days (28 nights).
They are expected at the clinical research center at 14:00 h in the afternoon prior to the day of administration of study compound. They 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 volunteers will leave the clinical research center on Day 28.
The participation to the entire study, from pre-study screening until the post study screening, will be maximally 63 days.

During the study the volunteers will receive GRC 17536 or placebo as oral tablets with 240 milliliters of tap water after consumption of a meal.
On Day 1 and Day 21 they will have to fast until 4 hours after administration

of the morning dose. Then they will receive a lunch. During fasting and after intake of the study compound, they are allowed to drink water, except from the time of study drug administration until 1 hour after study drug administration (apart from the water taken with the dose). In addition, the volunteers will have to fast for 1 hour after the evening dose. For subjects receiving 360 mg GRC 17536 or placebo, fasting restrictions as described above are also applicable on Day 20.

One of the investigators will inspect the hands and mouth after study compound intake.

Intervention

n.a.

Study burden and risks

During the investigation, various assessements will be done that can be experienced as more or less stressful.
Blood draw and the ECG can be experienced as stressful in this respect.

Contacts

Public
Glenmark Pharmaceuticals SA

Chemin de la Combeta 5
La Chaux-de-Fonds 2300
CH
Scientific
Glenmark Pharmaceuticals SA

Chemin de la Combeta 5
La Chaux-de-Fonds 2300
CH

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

healthy male subjects
18 - 45 years of age, inclusive
BMI 18.0 - 28.0 kilograms/meter2, inclusive
weight at least 50 kilograms

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:	Open (masking not used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-03-2015
Enrollment:	28

Type:	Actual

Ethics review

Approved WMO Date:	12-03-2015
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	23-03-2015
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	02-04-2015
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	EUCTR2015□000234□30-NL
CCMO	NL52767.056.15