A single-center, open-label study to evaluate the absorption, distribution, metabolism and excretion (ADME) and pharmacokinetics of QBW251 following a single oral dose of [14C]QBW251 in healthy male subjects at steady state conditions.

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

Summary

ID

NL-OMON46062

Source
ToetsingOnline

Brief title
QBW251 human ADME study at steady state in healthy male subjects

Condition

- Other condition

Synonym
COPD, lung diseases

Health condition

Longaandoeningen

Research involving
Human

Sponsors and support

Primary sponsor: Novartis Pharma AG
Source(s) of monetary or material Support: Farmaceutische Industrie.

Intervention

Keyword: ADME, COPD, QBW251

Outcome measures

Primary outcome

To determine the rates and routes of excretion of [14C]QBW251 related

radioactivity, including mass balance of total drug-related radioactivity

in urine and feces following a single 400 mg oral dose of [14C]QBW251 at steady

state in healthy volunteers.

To determine the pharmacokinetics of total radioactivity in blood and plasma.

To characterize the plasma pharmacokinetics of QBW251 and known key

metabolites, if applicable.

Secondary outcome

To assess the safety and tolerability of multiple oral doses of 400 mg of

QBW251 administered to healthy male subjects

Study description

Background summary

QBW251 is a new compound that may eventually be used for the treatment of chronic obstructive pulmonary disease (COPD), cystic fibrosis (CF) or other serious lung diseases. QBW251 is a so called CFTR potentiator. CFTR stands for cystic fibrosis transmembrane conductance regulator. CFTR forms a kind of channel in the cell wall (~transmembrane), that regulates the flow (~conductance) of water and salt in and out of cells in your body.

CFTR regulates the production of thin, flowing mucus. If CFTR is not working properly this can result in thick, sticky mucus. This can affect multiple organs, such as lungs, digestive system and reproductive organs. QBW251 enhances the function of CFTR, and this is thought to reduce the decline of lung function in CF patients and possibly improve long function in other serious lung diseases as well.

Study objective

The purpose of this study is to investigate how safe the new compound QBW251 is and how well it is tolerated when it is administered to healthy volunteers. QBW251 has been administered to humans before. It has also been previously tested in the laboratory and on animals.

It will also be investigated how quickly and to what extent the research compound QBW251 is absorbed and eliminated from the body (this is called pharmacokinetics). QBW251 will be labelled with 14 Carbon (14C) and this means that it is radioactive. In this way QBW251 can be traced in blood, urine and feces. In addition, the effect of QBW251 on the body will be investigated.

In addition, the effect of your genetic information on how the body responds to QBW251 will be investigated (this is called pharmacogenetics). This is an optional part of this study. If the volunteer does not wish to donate sample(s) for genetic research, it will not prevent them from being in the study.

Study design

The actual study will consist of 1 period during which the volunteers will stay in the research center for a maximum of 19 days (18 nights).

Day 1 is the first day of administration of the study compound. They are expected at the research center at 14:00 h in the afternoon prior to the day of first administration of the study compound (on Day -1).

The participation in the entire study, from the screening until the last follow-up visit, will depend on the amount of radioactivity left in urine and feces at the end of the study (Day 12). The amount of radioactivity in urine and feces will be measured daily from Day 5 onwards. If, from Day 12 onwards, the radioactivity levels in urine and feces are below the pre-defined levels, the volunteers will be allowed to leave the research center in the morning of Day 13. They will leave the research center on Day 18 at the latest.

They should be aware that when radioactivity levels are still above pre-defined levels on Day 18, they will return for a maximum of 4 additional 24hour visits in the clinical research center: on Days 20 - 21, 23 - 24 , 26 - 27 and 32 - 33. They will be informed if these 24-hour visits will take place.

The volunteer should be aware that for the overnight visits they will have to collect your urine and feces during the 24 hours before the visit and bring these to the research center with them. And also during these visits the urine and feces will be collected.

Intervention

Not applicable.

Study burden and risks

Pain, minor bleedings, bruises, possibly an infection.

Contacts

Public
Novartis Pharma AG

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CH
Scientific
Novartis Pharma AG

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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 male subjects
18 - 55 years of age
weight at least 55 kilograms, and no more than 120 kg
(BMI) 18 - 30 kilograms/meter2
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

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-11-2018
Enrollment:	6
Type:	Actual

Ethics review

Approved WMO Date:	09-10-2018
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	24-10-2018
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
EudraCT	EUCTR2018-001841-15-NL
CCMO	NL67518.056.18