OPEN-LABEL, NON-RANDOMIZED STUDY INVESTIGATING THE EXCRETION BALANCE, PHARMACOKINETICS, AND METABOLISM OF A SINGLE INTRAVENOUS DOSE OF [14C]-LABELED RO7223280 IN HEALTHY MALE PARTICIPANTS

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Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON51844

Source
ToetsingOnline

Brief title
Excretion balance, PK, and metabolism of 14C-labeled RO7223280

Condition

- Other condition

Synonym
treatment of infections caused by bacterium A. baumannii.

Health condition

infections caused by bacteria A. baumannii

Research involving
Human

Sponsors and support

Primary sponsor: F. Hoffmann-La Roche Ltd.
Source(s) of monetary or material Support: Pharmaceutical Industry

Intervention

Keyword: 14C RO7223280, infections caused by bacterium A. baumannii.

Outcome measures

Primary outcome

To characterize mass balance, rates, and routes of elimination of

[14C/12C]-labeled RO7223280, using conventional analytical methods (and

accelerator mass spectrometry [AMS] if necessary)

To assess the pharmacokinetics (PK) of total drug-related [14C]-radioactivity,

[12C] RO7223280 and its metabolite(s), as appropriate, using conventional

analytical methods (and AMS, if necessary)

Secondary outcome

To identify and quantify the metabolic profiles of RO7223280 in plasma, blood

pellet (if appropriate), urine, and feces on the basis of [14C]-radioactive

metabolic profiling, and characterize any major metabolite(s), using

conventional analytical methods (and AMS, if necessary)

To assess the safety and tolerability of a single intravenous dose of RO7223280

in healthy participants

Study description

Background summary

RO7223280 is a new compound that may potentially be used for the treatment of infections caused by bacterium A. baumannii. This bacterium has high rates of resistance to multiple antibiotics. RO7223280 targets an essential bacterial process in A. baumannii which is not targeted by currently available antibiotics. This bacteria type is most commonly found in hospitals in people with a compromised immune system. Furthermore, it is prevalent in Asia, parts of Europe, the Middle East and South America.

Study objective

In this study we will investigate how quickly and to what extent RO7223280 is distributed, metabolized, and eliminated from the body. For this study, RO7223280 is radioactively labelled with carbon-14 (14C). In this way RO7223280 can be traced in blood, urine, and feces.

We also investigate how safe the new compound RO7223280 is and how well it is tolerated when it is used by healthy participants.

We also look at the effect of your genetic information on your body*s response to RO7223280. This part of the study is mandatory.

At the time of writing this form, there are two ongoing studies with RO7223280 in healthy adult participants.

Study design

The study lasts a maximum of 8 weeks from the inspection to the follow-up check.

For the research it is necessary to stay in the research center for 1 period of at least 16 days (15 nights). The volunteer may leave the research center on Day 15 if the body has excreted at least 95% of the radioactivity. If the total amount of radioactivity excreted in urine and faeces on Day 15 is below this limit value, the stay may be extended by 7 days to Day 22. After this there is one more follow-up visit to the research center. This short visit will take place approximately 7 days (5-9 days) after the last urine and fecal samples have been collected.

Day 1 is the day on which the study drug is received. We expect the volunteer

at the study center on the day prior to the administration of the study drug. You must report to the research center between 9:30 a.m. and 2:00 p.m. One leaves the study center on either Day 15 or Day 22 of the study.

The volunteer receives 1000 mg of 14C labeled RO7223280 as a 1 hour intravenous infusion.

Intervention

Not applicable.

Study burden and risks

Blood draw
Blood draws may hurt or cause bruising. Using an indwelling cannula can sometimes cause inflammation, swelling, hardening of the artery, or blood clotting and bleeding around the puncture site. In some individuals, a blood draw can sometimes cause paleness, nausea, sweating, slow heart rate, or drop in blood pressure with dizziness or fainting.

All in all, from the inspection to the follow-up check, we take up to 410 milliliters (mL) of blood from you. This amount does not cause any problems in adults. If the investigator deems this necessary to ensure the safety of the participant, additional samples may be taken for any additional testing. If this happens, the total amount of blood drawn may be more than the amount indicated above.

ECG
To make a heart film, electrodes are placed on the arms, chest and legs. Prolonged use of these electrodes may cause skin irritation.

Coronavirus test
Samples for the coronavirus test will be taken with cotton swabs at the back of the nose and throat. Collecting the samples only takes a few seconds, but can cause discomfort and discomfort. Taking a sample from the back of the throat may result in gagging. When the sample is taken at the back of the nose, you may experience a stinging sensation and the eyes may water.

Contacts

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Grenzacherstrasse 124

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CH

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Healthy Male participants aged 35 to 64 years (inclusive) at screening
Participants must weigh at least 50 kg and have a BMI 18-32 kg/m2 (inclusive) at screening

Exclusion criteria

1. History of any clinically significant gastrointestinal, renal, hepatic, broncho pulmonary, neurological, psychiatric, cardiovascular, endocrinological, hematological or allergic disease, metabolic disorder, cancer, or cirrhosis
2. Concomitant disease or condition that could interfere with, or treatment of which might interfere with, the conduct of the study, or that would, in the opinion of the Investigator, pose an unacceptable risk to the participant in this study, including but not limited to, any major illness within 1 month before the screening examination or any febrile illness within 1 week prior to screening and up to first study drug administration
3. History or evidence of any medical condition potentially altering the absorption, distribution, metabolism, or elimination of drugs. Surgical history of the gastrointestinal tract affecting gastric motility or altering the gastrointestinal tract (with the exception of uncomplicated appendectomy and

hernia repair)
4. History or presence of clinically significant ECG abnormalities based on the average of the triplicate ECG recordings (e.g., PQ/PR interval * 210 ms, QTcF * 450 ms) or cardiovascular disease (e.g., cardiac insufficiency, coronary artery disease, cardiomyopathy, congestive heart failure, family history of congenital long QT syndrome, family history of sudden death)
5.History of malignancy

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	13-07-2022
Enrollment:	6
Type:	Actual

Ethics review

Approved WMO Date:	01-06-2022
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	05-07-2022
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	EUCTR2022-001155-16-NL
CCMO	NL81447.056.22

Study results

Date completed: 02-09-2022

Results posted: 06-04-2023

First publication
01-01-1900

URL result
URL
Type
int
Naam
M2.2 Samenvatting voor de leek M2.a. Lay Person Summary Dutch Jul2023
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Naam
M2.2 Samenvatting voor de leek M2.a. Lay Person Summary Dutch Jul2023
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Naam
M2.2 Samenvatting voor de leek M2.b. Lay Person Summary English Jul2023
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