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# A study to assess the period effect (and the effect of food) on processing by the body of RO7268489 following single oral-dose administration in healthy participants

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| **Submission date**<br>06/07/2023 | **Recruitment status**<br>No longer recruiting | [X] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[_] Results<br>[_] Individual participant data<br>[X] Record updated in last year |
| **Registration date**<br>10/07/2023 | **Overall study status**<br>Completed | |
| **Last Edited**<br>03/10/2024 | **Condition category**<br>Other | |

## Plain English summary of protocol

Background and study aims
RO7268489 (study drug) is an experimental drug, which means that Health Authorities (like the U.S. Food and Drug Administration and European Medicines Agency) have not approved RO7268489 for the treatment of any disease yet. The purpose of this study is to investigate how quickly and to what extent RO7268489 is taken up, modified, distributed, and removed from the body (this is called pharmacokinetics or PK). The study will also assess if PK is different if RO7268489 is given a second time and test if there is a difference in PK when RO7268489 is given under fasted or fed conditions (i.e., after fasting or after a meal). This study also aims to find out whether RO7268489 at a dose of 1 mg has any effects (good or bad) on healthy participants.

Who can participate?
Healthy males and females of 18 to 54 years of age

What does the study involve?
Participants will have to be a part of this study for approximately 92 days. This study will be conducted in two parts, Part 1 and Part 2. Based on when the participants enrol in the study, they may be placed in any one part of the study. Both parts of the study will have the following periods:
1. Screening Period: Participants will have to undergo some tests and/or procedures before the study starts to make sure that they are eligible for taking part in the study. It may take up to 8 weeks to complete the screening procedures. The participants may have to visit the clinic more than once during this period.
2. In-Clinic Period: Parts 1 and 2 of the study are further divided into two periods, Period 1, and Period 2. In both study parts (1 and 2) participants will be admitted to the study centre twice, once during Period 1 and once during Period 2. During both periods, participants will be admitted two days before the study drug is administered (i.e., Day -2) and will stay in the clinical unit for 4 nights (5 days). They will be allowed to go back home 48 hours after study drug

administration (i.e., Day 3) and after completing all the study tests.
a. Part 1 [“Period Effect” (PE)]: Participants will receive a single dose of RO7268489 by mouth on Day 1 of Period 1 and Period 2 after an overnight fast of at least 10 hours. Between the two periods, participants will have 1 to 3 weeks’ time during which they will not receive the study medication, this is called the wash-out period.
Part 2 [“Food effect” (FE)]: RO7268489 will be administered to the participants 2 times: once under fasted conditions (overnight fasting) and once under fed conditions (after breakfast), with a washout period in between. Participants will be assigned by chance to receive the study drug first under fasted or fed conditions.
3. Ambulatory Visits: In both Parts 1 and 2, participants will have to report to the clinic on prespecified days for check-ups.
4. Follow-up Visit: The participant will have to come back for the final safety follow-up visit on Day 92 after the second study drug administration. This is to check on the participants' health after treatment is completed.

What are the possible benefits and risks of participating?
RO7268489 is an experimental drug and is being given purely for research purposes, it is not intended that participants will receive any benefit from this study. But the information learned from this study may be useful to treat future patients.
The participants may have side effects from the study drug or procedures used in this study. Side effects can vary from mild to very serious and may be different from person to person.
RO7268489 has had limited testing in humans, there may potentially also be side effects that are not known at this time. The known side effects of this drug, as well as potential side effects, are listed below.
1. Allergic reactions on treatment with RO7268489, which can be in the form of itching, difficulty breathing, a rash, and/or a drop in blood pressure.

There may be a risk in exposing an unborn child to study the drug, and all risks are not known at this time. Women who are pregnant, become pregnant, or who are currently breastfeeding, cannot participate in this study.

Where is the study run from?
F. Hoffmann-La Roche Ltd (USA)

When is the study starting and how long is it expected to run for?
February 2023 to March 2024

Who is funding the study?
F. Hoffmann-La Roche Ltd (USA)

Who is the main contact?
global.trial_information@roche.com

### Study website
https://forpatients.roche.com/en/trials/healthy-volunteers/a-single-center--open-label--adaptive--two-period--single-oral-d.html

# Contact information

### Type(s)
Public

### Contact name
Dr Clinical Trials

### Contact details
Building 1, Grenzacherstrasse 124
Basel
Switzerland
CH-4070
+41 616878333
global.trial_information@roche.com

# Additional identifiers

### EudraCT/CTIS number
2023-503528-25-00

### IRAS number

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
BP44618

# Study information

### Scientific Title
A single-center, open-label, adaptive, two-period, single oral dose, phase I study to assess the period effect (and the effect of food) on the pharmacokinetics of RO7268489 in healthy participants

### Study objectives
The purpose of this study is to assess the period effect on the pharmacokinetics (PK) of a single oral dose of RO7268489 in healthy participants. In addition, the study will also assess the effect of food on the PK of single oral doses of RO7268489 in healthy participants.

### Ethics approval required
Ethics approval required

### Ethics approval(s)
Approved 01/06/2023, BEBO Foundation for the Assessment of Ethics of Biomedical Research (Doctor Nassaulaan 10, Assen, 9401 HK, Netherlands; +31 (0) 592 405 871; info@stbebo.nl), ref: Not available

### Study design
Phase I open-label adaptive two period single-center study
Part 1: non-randomized two-period design
Part 2: randomized two-period cross-over design

## Primary study design
Interventional

## Secondary study design
Part 1: Non-randomized; Part 2: Randomized

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet
No participant information sheet available

## Health condition(s) or problem(s) studied
Healthy participants

## Interventions
Part 1: Participants will receive a single oral dose of RO7268489, 1 milligram (mg), on Day 1 of Period 1 after an overnight fast of at least 10 hours. Following a washout period of 1-3 weeks participants will then receive another single oral dose of RO7268489, 1 mg, on Day 1 of Period 2 under fasted condition.

Part 2: Fasted/Fed Sequence: Participants will receive a single oral dose of RO7268489, 1 mg, on Day 1 of Period 1 after an overnight fast of at least 10 hours. Following a washout period of 1-3 weeks participants will then receive a second oral dose of RO7268489, 1 mg, on Day 1 of Period 2 under fed condition i.e., after having breakfast.

Part 2: Fed/Fasted Sequence: Participants will receive a single oral dose of RO7268489, 1 mg, on Day 1 of Period 1 under fed condition i.e., after having breakfast. Following a washout period of 1-3 weeks participants will then receive a second oral dose of RO7268489, 1 mg, on Day 1 of Period 2 after an overnight fast of at least 10 hours.

## Intervention Type
Drug

## Pharmaceutical study type(s)
Pharmacokinetic

## Phase
Phase I

## Drug/device/biological/vaccine name(s)
RO7268489

## Primary outcome measure
1. Part 1: Area under the plasma concentration time curve (AUC) of RO7268489 (and its metabolite[s] as appropriate) calculated using standard non-compartmental methods from samples collected at pre-dose and multiple time-points post-dose from Day 1 up to follow-up visit on Day 92

2. Part 1: Maximum observed plasma concentration (Cmax) of RO7268489 (and its metabolite[s] as appropriate) calculated using standard non-compartmental methods from samples collected at pre-dose and multiple time-points post-dose from Day 1 up to follow-up Visit on Day 92
3. Part 2: AUC of RO7268489 (and its metabolite[s] as appropriate) under fasted and fed conditions calculated using standard non-compartmental methods from samples collected at pre-dose and multiple time-points post-dose from Day 1 up to follow-up visit on Day 92
4. Part 2: Cmax of RO7268489 (and its metabolite[s] as appropriate) under fasted and fed conditions calculated using standard non-compartmental methods from samples collected at pre-dose and multiple time-points post-dose from Day 1 up to follow-up visit on Day 92

### Secondary outcome measures
1. Parts 1 and 2: Number of participants with adverse events (AEs) and severity of AEs graded as mild, moderate and severe from screening up to follow-up visit on Day 92
2. Parts 1 and 2: Concentration of RO7268489 calculated using standard non-compartmental methods from samples collected at pre-dose and multiple timepoints post-dose up to Day 15
3. Parts 1 and 2: RO7268489-related change on pharmacodynamics (PD) biomarker measured using validated liquid chromatography coupled to tandem mass spectrometry (LC-MS/MS) method from samples collected at pre-dose and multiple timepoints post-dose up to Day 22
4. Parts 1 and 2: RO7268489-related change on PD biomarker in serum measured using validated LC-MS/MS method from samples collected at pre-dose and multiple time-points post-dose up to Day 22

### Overall study start date
21/02/2023

### Completion date
20/02/2024

## Eligibility

### Key inclusion criteria
1. Male or female participants who are overtly healthy (defined by absence of evidence of any active or chronic disease)
2. Body mass index (BMI) within the range of 18 to 32 kilograms per square meter (kg/m2) (inclusive)

### Participant type(s)
Healthy volunteer

### Age group
Adult

### Lower age limit
18 Years

### Upper age limit
54 Years

### Sex
Both

### Target number of participants
36

### Total final enrolment
24

### Key exclusion criteria
1. History of malignancy in the past 5 years
2. History or evidence of any medical condition potentially altering the absorption, metabolism, or elimination of drugs.
3. Vaccination within 6 weeks prior to Day 1 including influenza and/or SARS-CoV-2/ COVID-19 vaccination.

### Date of first enrolment
18/07/2023

### Date of final enrolment
11/10/2023

## Locations

### Countries of recruitment
Netherlands

### Study participating centre
**ICON**
Netherlands
9728

## Sponsor information

### Organisation
F. Hoffmann-La Roche

### Sponsor details
Building 1, Grenzacherstrasse 124
Basel
Switzerland
CH-4070
+41 616878333
global.trial_information@roche.com

### Sponsor type
Industry

**Website**
https://www.roche.com/about/

# Funder(s)

**Funder type**
Industry

**Funder Name**
F. Hoffmann-La Roche

**Alternative Name(s)**
Hoffman-La Roche, F. Hoffmann-La Roche Ltd.

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
For-profit companies (industry)

**Location**
Switzerland

# Results and Publications

**Publication and dissemination plan**
Planned publication in a high-impact peer-reviewed journal

**Intention to publish date**
30/03/2025

**Individual participant data (IPD) sharing plan**
The datasets generated during and/or analysed during the current study are not expected to be made available due to participant-level data not being a regulatory requirement.

**IPD sharing plan summary**
Not expected to be made available