ForPatients
by Roche

Healthy Volunteers

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

Trial Status	Trial Runs In	Trial Identifier
Recruiting	1 Countries	BP44618

The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

Trial Summary:

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

F. Hoffmann-La Roche Ltd (USA)
Sponsor

Phase 1
Phase

BP44618
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
Both	18 to 54 years (inclusive)	Yes

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 24 weeks. 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 center 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 (1-3 weeks). 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 how the drug is eliminated from the body and 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.

ForPatients
by Roche

Where is the study run from?

F. Hoffmann-La Roche Ltd (Switzerland)

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 (Switzerland)

Who is the main contact?

global-roche-genentech-trials@gene.com