ForPatients
by Roche

Healthy Volunteers

A Phase I randomized, investigator/participant-blind, adaptive, single ascending dose, placebo-controlled study to investigate the safety, tolerability, pharmacokinetics, and food effects of RO7308480 following oral administration in healthy participants

Trial Status	Trial Runs In	Trial Identifier
Not Yet Recruiting	1 Countries	BP43318

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

Trial Summary:

Study to evaluate the safety, tolerability, and effect of the body and food on RO7308480 following oral administration in healthy participants

F. Hoffmann-La Roche Ltd (USA)
Sponsor

BP43318
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
Both	18 to 55 years	Yes

Background and study aims

This is the first study where the drug RO7308480 will be given to humans. The aims of this study are to test the safety of RO7308480 at different dose levels, determine how well it is tolerated by the participants; measure how the body absorbs, distributes, and gets rid of it (this is called pharmacokinetics); and to determine the effect that food can have on its pharmacokinetics. The study results will be used to support further clinical development of RO7308480.

Who can participate?

Healthy volunteers between 18 to 55 years of age

What does the study involve?

This study consists of two parts, Part 1, and Part 2. Participants will be assigned to either Part 1 or Part 2.

Part 1

Participants may be asked to be in the study for about 8 weeks in Part 1. This includes:

1. A screening visit within 28 days before treatment administration where tests will be done to check if the participants are eligible to take part in the study

2. An inpatient stay at the clinic for 8 days and 7 nights (from 2 days before until 6 days after treatment)

3. Six walk-in visits on Days 7, 8, 10, 12, 14, and 28 after treatment.

Part 1 or the “single-ascending dose” stage will evaluate the safety, tolerability, and pharmacokinetics of RO7308480. Participants will be divided into seven different groups, with each group receiving a higher dose level than the preceding group. A higher dose level will only be administered in participants after the lower dose levels have been shown to be safe and well-tolerated in previous participants. Each group will have a maximum of 12 participants of which 9 will receive RO7308480 and 3 will receive a placebo (a drug without the active substance).

Each of the seven dose levels will be split into two groups. Two participants will be dosed on Day 1 (one participant will receive RO7308480 and one participant will receive a placebo). The rest of the group (a minimum of five participants on active treatment and a minimum of one participant on placebo) will be dosed no earlier than 24 hours later.

Participants will be given RO7308480 or matching placebo capsules to be swallowed whole with about 240 ml water at room temperature on the morning of Day 1 after an overnight fast of at least 10 hours.

Part 2

Participants may be asked to be in the study for about 14 weeks in Part 2. This includes:

1. A screening visit within 28 days before treatment administration where tests will be done to check if the participants are eligible to take part in the study

2. An inpatient stay at the clinic twice – each time for 7 days and 6 nights (from 1 day before each of the treatments until 6 days after each treatment)

3. A period in between the two treatment administrations of 14 to 28 days where the drug is expected to be eliminated after the first administration (wash-out)

4. Six ambulatory visits on Days 7, 8, 10, 12, 14, and 28 after the second treatment.

Part 2 or the “food effect” (FE) assessment will evaluate the effect of food on the levels of RO7308480 in the body, whether and how food affects the speed and extent with which the body absorbs, distributes, and gets rid of RO7308480. A maximum of 12 participants will be enrolled in Part 2.

There will be two study periods in Part 2. In the first period, six participants will receive RO7308480 under fasted conditions (overnight fasting) and the remaining six will receive the same dose of the drug under fed conditions (after breakfast). In the second period, participants will receive the same dose of RO7308480 under the other condition. In other words, if the first study drug administration was done under fasted conditions, the second one will be done in the fed condition, and vice-versa. There will be an interval of about 14 to 28 days between both periods (wash-out period).

What are the possible benefits and risks of participating?

Participants will not receive any benefit from participating in this study, but the information that is learned may help further the clinical development of RO7308480.

Participants may experience side effects from the treatments or procedures in this study. Side effects can vary from mild to very serious and may be different from person to person. RO7308480 has not yet been tested in humans, and the side effects of this drug are not known at this time. Based on laboratory studies and knowledge of other drugs, the potential risks listed below may occur.

1. Allergic reactions such as itching, difficulty breathing, a rash, and/or a drop in blood pressure

2. Central nervous system related effects

3. Slurred speech (e.g., mumbling)

4. Mental disturbances such as mood disorders, prolonged periods of extreme sadness, agitation, and irritability

5. Symptoms of overdose may include sedation, unconscious state, and slow or ineffective breathing

There may be a risk in exposing an unborn child to the study treatment, and not all potential consequences are known at this time. Women and men must take precautions

to avoid exposing an unborn child or a breastfed baby to the study treatment. Participants who are pregnant, become pregnant, or are currently breastfeeding cannot take part 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?

November 2021 to July 2022

Who is funding the study?

F. Hoffmann-La Roche Ltd (USA)

Who is the main contact?

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