ForPatients
by Roche

Healthy Volunteers

A single-center, non-randomized, open-label, parallel group, adaptive, phase I positron emission tomography (PET) study to assess the brain occupancy following single oral doses of RO7268489 in healthy participants

Trial Status	Trial Runs In	Trial Identifier
Recruiting	1 Countries	BP44712

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 brain occupancy following a single dose of RO7268489 in healthy participants

F. Hoffmann-La Roche Ltd
Sponsor

BP44712
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
Both	18 to 55 years	Yes

Background and study aims:

RO7268489 is an experimental new medicine. An experimental drug means that Health Authorities (like the U.S. Food and Drug Administration) have not yet approved RO7268489.

The purpose of this study to find out how quickly and to what extent RO7268489 goes to the brain, and how long it will stay in the brain. The study will also test what happens to RO7268489 once it is in the body, what RO7268489 does to the body and the safety of RO7268489 at different dose levels to find out what effects, good or bad, RO7268489 has on healthy participants.

RO7268489's location and movement within the body can be traced using the images (scans) that are taken with a method called positron emission tomography (PET). To make RO7268489 visible on the scans, it will be given with a radioactive medicine used with PET imaging (tracer). The tracer will be given as a single injection directly into a vein before each of the 3 PET scans.

Who can participate?

Healthy participants between 18 - 55 years of age

What does the study involve?

Participants will need to be a part of the study for about 8 to 14 weeks (including the screening period and the safety follow-up visit).

Screening period: Participants will be screened to check if they are eligible to participate in the study. Screening period will take place from 42 days to 2 days before the start of treatment.

In Clinic Period: Participants will have to get admitted to the clinic 1 day before the study treatment (RO7268489) administration and will have to stay for up to 3 days after receiving the study treatment. During this time participants will receive study treatment by mouth in the form of a capsule. Participants will also receive the tracer by injection before the PET scan.

Ambulatory Visit: Participants will have to revisit the clinic after getting discharged for check-ups and PET scans after the study treatment is completed. Ambulatory visits will occur from Day 4 up to Day 55 after the treatment administration.

Follow Visit: Participants' overall health and occurrence of any side effects will be assessed during a follow up visit that may take place between Day 14 to Day 56.

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.

Participants may have side effects from the drug or procedures used in this study, and they can be mild to severe, and they can vary from person to person.

Risks Associated with RO7268489:

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. Allergic reactions on treatment with RO7268489, which can be in the form of itching, difficulty breathing, a rash, and/or 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

Side Effects Associated with PET Tracer:

The tracer, is labelled with a radioactive substance. However, the dose used is very small and within acceptable limits.

Side Effects Associated with MRI Scan:

A magnetic resonance imaging (MRI) scan is a medical procedure using powerful magnets, radio waves, and a computer to make detailed images of the organs in the body so participants with an artificial heart valve, metal plate, pin, or other metallic objects in their body (including gunshot or shrapnel) may not be eligible. The risks or side effects associated with undergoing an MRI scan are minimal for most participants. MRI scanners are quite closed in and may be unpleasant for people who have a fear or strong dislike of enclosed spaces.

Where is the study run from?

F. Hoffmann-La Roche Ltd (Switzerland)

Who is funding the study?

F. Hoffmann-La Roche Ltd (Switzerland)

Who is the main contact?

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