ForPatients
by Roche

Healthy Volunteers

A Study to See How RO7763505 Works and How Safe it is When Given to Healthy People and People With Stable Heart Disease

Trial Status	Trial Runs In	Trial Identifier
Recruiting	1 Country	NCT07495813 2025-524693-42-00 BP46355

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

A Phase I, Randomized, Double-Blind, Adaptive, Placebo-Controlled, Single- Ascending Dose and Multiple-Ascending Dose, Parallel Study to Investigate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Food Effect of RO7763505 Following Oral Administration in Healthy Participants and Patients With Stable Coronary Artery Disease

Trial Summary:

This study will evaluate safety, tolerability, pharmacokinetics (PK) and pharmacodynamics (PD) of single ascending doses (SAD) (Part 1a), multiple ascending doses (MAD) (Part 1b), and the food effect (Part 1c) of RO7763505 in healthy adult participant. In Part 2, the safety, tolerability, PK and PD of multiple doses of RO7763505 in participants with stable coronary artery diseases (CAD).

Hoffmann-La Roche Sponsor	**Phase 1** Phase

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Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years & # 75 Years	Accepts Healthy Volunteers

Inclusion Criteria:

Part 1:

- Healthy biologically male and female participants of nonchildbearing potential or childbearing potential with no clinically relevant findings on physical examination at screening or baseline (assessed either on Day -2 or Day -1), including detailed medical and surgical history, vital signs, 12-lead electrocardiogram (ECG), hematology, blood chemistry, serology, and urinalysis
- No suspicion of cognitive impairment/dementia as judged by the Investigator

Part 2:

- Myocardial infarction before the screening visit
- Objective imaging evidence (coronary computed tomography [CT] angiography or invasive angiography) of coronary atherosclerosis Participants who underwent percutaneous coronary intervention (PCI) or coronary artery bypass graft (CABG) are eligible if the procedure was done >6 months prior to screening
- A diagnosis of stable CAD, defined as being on stable guideline-directed medical therapy (GDMT) if tolerated for at least 90 days prior to screening with no planned changes or scheduled interventions during the study
- QTc of <= 450 milliseconds (ms) as determined by a single 12-lead ECG recording. If the initial ECG result of the triplicate is exclusionary, consecutive repeat ECG results must be within the acceptable limits. In participants with a stable bundle branch block where the QRS duration is > 120 ms, the QTcF will be calculated as: QTcF - (QRS - 100 ms)

Exclusion Criteria:

Part 1:

- Any condition or disease detected during the medical interview/physical examination that would render the participant unsuitable for the study, place the participant at undue risk, or interfere with the ability of the participant to complete the study in the opinion of the Investigator
- Vaccination within 28 days prior to Day 1 (non-live vaccines including influenza vaccination are permitted 14 days prior to Day 1) or planned before the end of the study. Investigators are advised to review the immunization status of participants who are considered for treatment with RO7763505 and follow local/national guidance for adult vaccination against infectious disease as they deem relevant
- Positive result on human immunodeficiency virus (HIV)-1 and HIV-2, hepatitis B virus (HBV) (either hepatitis B surface antigen [HBsAg] or hepatitis B core antibody [HBcAb]), hepatitis C virus (HCV) antibody test, or tuberculosis (TB)

Part 2:

- Individuals with New York Heart Association (NYHA) Class III or IV heart failure
- Known or suspected immunocompromised state
- Treatment with any investigational therapy within 28 days or within five drug-elimination half-lives (whichever is longer; or longer than either if required by local regulations; if the half-life is unknown, the 90-day period applies) prior to Day 1, calculated from the day of the follow-up from the previous study