ForPatients
by Roche

Healthy Volunteers

A Study Investigating the Effect of Different Approved Medications on How the Body Processes the Study Compound RO7795081

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Country	NCT06809608 2024-517360-37-00 BP45670

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:

An Open-Label, Fixed Sequence Study to Investigate the Effect of Multiple Oral Doses of Itraconazole, Multiple Oral Doses of Gemfibrozil, and Single Oral Dose of Cyclosporine, on the Pharmacokinetics of a Single Oral Dose of RO7795081 in Healthy Participants

Trial Summary:

This is a single-center, non-randomized, open-label, cross-over study in healthy male and female participants. Part 1 of the study has a 2-period (a single fixed sequence) design and will investigate the impact of itraconazole on the pharmacokinetics (PK) of RO7795081 in healthy participants. A maximum of up to 25 participants will be enrolled in Part 1 and sequentially undergo Period 1 (RO7795081 alone) followed by Period 2 (RO7795081 with itraconazole). Part 2 of the study has an adaptive design with up to 4 periods (a single fixed sequence) and will investigate the impact of gemfibrozil and cyclosporine on the PK of RO7795081 in healthy participants. A maximum of up to 25 participants will be enrolled in Part 2 and sequentially undergo Period 1 (RO7795081 alone) followed by Period 2 (RO7795081 with gemfibrozil), Period 3 (RO7795081 with cyclosporine 200 mg), and finally Period 4 (RO7795081 with cyclosporine #600 mg).

Hoffmann-La Roche
Sponsor

Phase 1
Phase

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Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years & # 65 Years	Accepts Healthy Volunteers

Inclusion Criteria:

- Healthy biological males or females, defined by absence of evidence of any active or chronic disease
- Ability to communicate with the Investigator
- Able and willing to attend the necessary visits to the study site
- Not under judicial supervision, guardianship, or curatorship
- Body mass index (BMI) of 18 to 32 kg/m^2 inclusive, and a body weight of #50 kilograms at screening

Exclusion Criteria:

- 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
- History or presence of any clinically significant cardiovascular, bronchopulmonary, hepatic, renal, gastrointestinal, endocrinological, hematological, neurological, psychiatric, genitourinary, metabolic disorders, allergic diseases, cancer, or cirrhosis
- History or evidence of any medical condition capable of significantly altering the absorption, metabolism, or elimination of drugs
- Surgical history of the GI tract affecting gastric motility or altering the GI tract (with the exception of uncomplicated appendectomy and cholecystectomy)
- History of malignancy in the past 5 years, except for fully treated local basal carcinoma, or fully treated carcinoma in situ of cervix
- History of convulsions (other than benign febrile convulsions of childhood) including epilepsy, or personal history of significant cerebral trauma or central nervous system infections (e.g., meningitis)
- Any major illness (in the opinion of the Investigator) within 1 month before the screening examination or any febrile illness (in the opinion of the Investigator) within 1 week prior to screening and within 1 week prior to admission
- History of clinically significant hypersensitivity (e.g., drugs [including but not limited to lidocaine, caffeine, povidone-iodine], excipients) or clinically significant allergic reactions
- Have an abnormal blood pressure at the time of screening and on baseline, confirmed by the average of 3 blood pressure measurements, properly measured with well-maintained equipment: supine systolic blood pressure <90 millimetres of mercury (mmHg) or >140 mmHg or diastolic blood pressure <45 mmHg or >90 mmHg
- Confirmed (based on the average of # 3 consecutive measurements) resting pulse rate greater than 100 or less than 40 beats per minute at the time of screening and on baseline
- History or presence during screening and baseline of clinically significant ECG abnormalities before study drug administration (e.g., PQ/PR interval >210 milliseconds (ms), QTcF >450 ms [>470 ms female participants], based on the average interval on triplicate ECGs) or cardiovascular disease (e.g., cardiac insufficiency, coronary artery disease, cardiomyopathy, congestive heart failure, family history of congenital long QT syndrome, family history of sudden death)
- Clinically significant abnormalities in laboratory test results (including hepatic and renal panels, complete blood count, chemistry panel, and urinalysis). In the case of uncertain or questionable results, tests performed during screening may be repeated before randomization to confirm eligibility
- Any suspicion or history of alcohol abuse and/or suspicion of regular consumption of drug of abuse (including cannabis-containing products) and/or evidence of current or previous drug of abuse (including cannabis-containing products) dependency within 5 years before screening
- Participants who, in the Investigator's judgment, pose a suicidal or homicidal risk, or any participant with a history of suicidal or homicidal attempts
- Bipolar disorder, schizophrenia or any other serious psychiatric condition (e.g., Axis I Disorder, DSM-IV-TR)

- Uncontrolled behavioral symptoms incompatible with compliance or evaluability (e.g., severe agitation, lack of impulse control, violence, and severe dysphoria)
- Any other medical condition not previously mentioned that could be expected to progress, recur, or change to such an extent that it could bias the assessment of the clinical or mental status of the participant to a significant degree or put the participant at special risk
- Presence of any acute or chronic illness or history of chronic illness not otherwise mentioned elsewhere and sufficient to invalidate the participant's participation in the trial or make it unnecessarily hazardous. Such conditions may include clinically significantly impaired endocrine, thyroid, hepatic, respiratory or renal function for any reason, unstable diabetes mellitus and insulin-dependent diabetes mellitus, clinically significant cardiovascular disease, pheochromocytoma, or history of any psychotic mental illness
- Known active or uncontrolled bacterial, viral, fungal, mycobacterial infection or other infection, excluding fungal infection of nail beds, including participants exhibiting symptoms consistent with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) within 6 weeks prior to Period 1 Day 1
- Vaccination within 6 weeks prior to Period 1 Day 1, including influenza and/or SARS-CoV-2/COVID-19 vaccination
- Use of any prohibited medications and food before study start and during the study
- Participants likely to need concomitant medication during the study period, with some exceptions
- Participation in an investigational drug or device study within 90 days prior to dosing, as calculated from the day of follow-up from the previous study or within 30 days
- Participation in an investigational drug study involving any therapeutic monoclonal antibody, protein derived from a monoclonal antibody, immunoglobulin therapy, or vaccine (with the exception of approved SARS-CoV-2/ COVID-19 vaccination) within 6 months prior to dosing (unless it can be documented that the participant was randomized to placebo) as calculated from the day of last dosing from the previous study
- Positive test for drugs of abuse or alcohol
- Positive result on human immunodeficiency virus (HIV)1 and HIV2, hepatitis C virus, or hepatitis B surface antigen
- Any suspicion or history of regular alcohol consumption for 1 month before screening defined as #21 drinks per week for males and #14 drinks per week for females
- Smokers who smoke more than 5 cigarettes per day or equivalent amount of tobacco (including e-cigarettes/vapes) as determined by history, and unable or unwilling not to smoke during the in-clinic period
- Donated over 450 mL of blood or blood products or had significant blood loss within 3 months prior to screening
- Dietary restrictions that would prohibit the consumption of standardized meals
- History of hypersensitivity to itraconazole (or any other triazole antifungal agent), gemfibrozil, cyclosporine, or their formulation ingredients
- Inability or unwillingness to meet study requirements
- Predictable poor compliance or inability to communicate well with the Investigator