ForPatients
by Roche

Healthy Volunteers

A Study To Investigate The Safety, Tolerability And Pharmacokinetics (PK) Of RO7223280 Following Intravenous Administration In Healthy Participants

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Country	NCT04605718 BP41732

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 Randomized, Sponsor-Open, Adaptive, Single- And Multiple-Ascending Dose, Placebo-Controlled Study To Investigate The Safety, Tolerability, And Pharmacokinetics Of RO7223280 Following Intravenous Administration In Healthy Participants

Trial Summary:

The Study consists of 3 Parts: Part 1 (Single Ascending Dose/SAD), Part 2 (Multiple Ascending Dose/MAD), and Part 3 (Elderly). Part 1 will investigate the safety, tolerability and PK of single-ascending intravenous (IV) doses of RO7223280 in healthy participants. Part 2 will investigate the safety, tolerability and PK of multiple-ascending IV doses of RO7223280 in healthy participants. Part 2 will start after the initial completion of Part 1 (SAD). Progression from Part 1 to Part 2 will be based on a satisfactory review of all available safety, tolerability, and PK data by the Investigator and the Sponsor from Part 1. The starting dose for Part 2 will be administered as 1-hour IV infusion; as it has been established on the basis of all available safety, tolerability, and PK data in Part 1 (SAD). Part 3 will investigate the safety, tolerability and PK of a single IV dose of RO7223280 in healthy elderly participants. A single IV dose of RO7223280 administered over 1 hour was selected, within the range of previously explored doses in Part 1 (SAD).

Hoffmann-La Roche	Phase 1
Sponsor	Phase

NCT04605718 BP41732
Trial Identifiers

Eligibility Criteria:

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Gender	Age	Healthy Volunteers
All	#18 Years	Accepts Healthy Volunteers

Inclusion Criteria:

- Parts 1 (SAD) and 2 (MAD): 18 to 64 years of age, inclusive. Part 3 (Elderly): 65 years of age and older
- Healthy participants in Part 1 (SAD) and Part 2 (MAD). Health status is defined by absence of evidence of any active or chronic disease following a detailed medical and surgical history, a complete physical examination including vital signs, 12-lead ECG, hematology, blood chemistry, serology, coagulation, and urinalysis. Healthy participants in Part 3 (Elderly). Participants must be in reasonably good health as determined by the Investigator based on medical and surgical history, a complete physical examination including vital signs, 12-lead ECG, hematology,blood chemistry, serology, coagulation, and urinalysis. Participants with mild, chronic, stable disease (e.g., controlled hypertension, controlled diabetes mellitus) may be enrolled if deemed medically prudent by the Investigator.
- In Part 1 (SAD) and Part 2 (MAD) participants must weigh at least 50 kg and must have a body mass index (BMI) within the range of 18 to 32 kg/m^2 (inclusive). In Part 3 (Elderly), participants must weigh at least 50 kg with no restrictions regarding the BMI.
- During the treatment period and for at least 90 days after the final dose of RO7223280 or placebo, male participants (whether surgically sterilized or not) agree to remain abstinent (refrain from heterosexual intercourse), use contraceptive measures and refrain from donating sperm at least 90 days after last dose.

Exclusion Criteria:

- For Part 1 (SAD) and Part 2 (MAD), history of any clinically significant gastrointestinal, renal, hepatic, broncho-pulmonary, neurological, psychiatric, cardiovascular, endocrinological, hematological or allergic disease, metabolic disorder, cancer, or cirrhosis.For Part 3 (elderly), participants must be in reasonably good health as determined by the Investigator based on a detailed medical history. Participants with mild, chronic, stable disease and on stable medication may be enrolled if deemed medically prudent by the Investigator.
- In Part 1 (SAD) and Part 2 (MAD), use of glucocorticoids and other immunosuppressive medications is prohibited within 30 days (or within 5 times the elimination half-life, whichever is longer), prior to Day 1. In Part 3 (Elderly Cohort), the systemic use of glucocorticoids and other immunosuppressive medications is prohibited within 30 days (or within 5 times the elimination half-life, whichever is longer), prior to Day 1.
- Participation in an investigational drug medicinal product or medical device study within 30 days prior to screening or within 5 times the elimination half-life if known, whichever is longer.
- In Part 1 (SAD) and Part 2 (MAD), confirmed (based on the average of 3 consecutive measurements) systolic blood pressure (SBP) greater than 140 or less than 90 mmHg, and diastolic blood pressure (DBP) greater than 90 or less than 50 mmHg at screening. In Part 3 (Elderly), confirmed (based on the average of 3 consecutive measurements) systolic blood pressure (SBP) greater than 160 or less than 80 mmHg, and diastolic blood pressure (DBP) greater than 90 or less than 40 mmHg at screening.
- Confirmed (based on the average of 3 consecutive measurements) resting pulse greater than 100 bpm or less than 40 bpm at screening.
- Positive for HIV or Hepatitis B/C infections.
- Donation of blood or blood products for transfusion over 500 mL within 3 months prior to first study drug administration and for the duration of the study.
- Any clinically significant history of hypersensitivity or allergic reactions, either spontaneous or following study drug administration, or from exposure to food or environmental agents.