ForPatients
by Roche

Healthy Volunteers

A Study Investigating [14C]-Labeled RO7269162 in Healthy Male Participants

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Country	NCT06733298 BP45325

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:

Open-Label, Non-Randomized Study Investigating the Excretion Balance, Pharmacokinetics, and Metabolism of a Single Oral Dose of [14C]-Labeled RO7269162 in Healthy Male Participants

Trial Summary:

This study will investigate how RO7269162 labeled with a carbon tracer ([14C]) is absorbed, metabolized, and eliminated by the body after a single dose in healthy male volunteers.

Hoffmann-La Roche
Sponsor

Phase 1
Phase

NCT06733298 BP45325
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
Male	#35 Years & # 64 Years	Yes

Inclusion Criteria:

- Male participants aged 35 to 64 years of age (inclusive), at screening
- Body weight # 50 kg and body mass index within the range 18 to 30 kg/m2 (inclusive), at screening
- Male participants who, for 3 months after dosing of [14C]-RO7269162, agree to: remain abstinent (refrain from heterosexual intercourse) or use contraception as defined by the protocol with a partner that is a woman of childbearing potential; remain abstinent or use contraception with a pregnant female partner; refrain from donating sperm

Exclusion Criteria:

- History or evidence of any clinically significant gastrointestinal, renal, hepatic, broncho-pulmonary, neurological, psychiatric, cardiovascular, endocrinological, hematological, or allergic disease, metabolic disorder, cancer, or cirrhosis
- Any disease or condition that could interfere with the conduct of the study or pose an unacceptable risk to the participant
- History or evidence of any medical condition that could potentially alter the absorption, metabolism, or elimination of drugs
- Surgical history of the gastrointestinal (GI) tract affecting gastric motility or altering the GI tract (with the exception of uncomplicated appendectomy and hernia repair)
- History of malignancy
- Use of any prescription drugs, herbal supplements, and/or over-the-counter medication (OTC), dietary supplements (vitamins included) within 2 weeks before Day 1. Use of any prohibited food before study start and during the study as defined by the protocol
- Likely to need medication during the study period except for those defined by the protocol
- Are currently enrolled in, have participated in, or plan to participate in any other clinical study involving an investigational medicinal product or medical device study from within the 30 days directly preceding screening or within 5 times the elimination half-life, if known (whichever is longer), until completion of the follow-up visit
- Evidence of human immunodeficiency virus (HIV), hepatitis B, or hepatitis C
- Donation of blood or blood products for transfusion over 100 mL or significant blood loss within 2 months prior to screening through study completion, clinic discharge or early termination, inclusive. Donation of blood or plasma is not allowed throughout the entire study. Receipt of blood products within 2 months prior to Day -1 is not allowed
- Clinically significant history of hypersensitivity or allergic reactions
- Regular work with ionizing radiation or radioactive material, or exposure to ionizing radiation within 1 year prior to study drug administration