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A study to evaluate the safety, tolerability, disposition in the body, and effects on the body of RO7504109 in healthy participants

Submission date 15/05/2024	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 17/05/2024	**Overall study status** Ongoing	
Last Edited 11/03/2025	**Condition category** Other	

Plain English summary of protocol

Background and study aims
Inflammatory bowel disease (IBD) is a health condition that makes parts of the digestive system, like the stomach and intestines, become swollen. This can cause problems like tummy pain, loose stools, and, sometimes, bleeding. This study is testing a medicine called RO7504109. It is being developed as a possible treatment for IBD. RO7504109 is an experimental medicine. This means health authorities (like the U.S. Food and Drug Administration, European Medicines Agency, or Medsafe) have not approved RO7504109 for the treatment of any disease. This study aims to test the safety of RO7504109 after both single and multiple doses, what happens to RO7504109 once it is in the body, and what RO7504109 does to the body.

Who can participate?
Healthy people (males and females) of 18-65 years of age with a body weight of at least 50 kilograms (kg) can take part in the study.

People who are pregnant, or currently breastfeeding cannot take part in the study.

What does the study involve?
People will be screened to check if they can participate in the study. The screening period will take place 28 days to 1 day before the start of the treatment.

Everyone who joins this study will receive RO7504109 given either as an injection under the skin or an infusion into the vein. Participants in Group 1 will receive a single dose of RO7504109 or placebo on Day 1, whereas participants in Group 2 will receive a total of 5 doses of RO7504109 or placebo with dosing every 2 weeks (Q2W). Placebo is a substance that contains no active ingredients but looks the same as the study drug. This means that it does not have any direct effects on the body. Participants will have regular blood tests and will be checked for unwanted effects throughout the study.
This is a double-blind study. A double-blind study is a study where nobody knows which treatment is being given – neither the people in the study nor the team running it. This is done to make sure that the results of the treatment are not affected by what people expect from the

received treatment. However, the study doctor can find out which group the participant is in, if the participant's safety is at risk. During the study, the doctor will see participants during the overnight stays at the clinic for up to 2 nights after the treatment is given. Participants will have multiple follow-up visits after completing the study treatment, and a phone call on Day 10, during which the study doctor will check on the participant's well-being. The total time of participation in the study will be about 26 weeks for Group 1 and about 34 weeks for Group 2. Participants have the right to stop study treatment and leave the study at any time if they wish to do so.

What are the possible benefits and risks of participating?
RO7504109 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. However, the information collected in the study can help people with diseases in the future.

RO7504109 RO7504109 is currently being tested in humans, and few side effects of this drug are not known at this time. The study involves some risks to the participants. People interested in taking part will be informed about the risks, as well as any additional procedures or tests they may need to undergo. All details of the study will be described in an informed consent document. This includes information about possible risks from the treatment.

Risks associated with the study drug

Participants may have unwanted effects of the drug used in this study. These unwanted effects can be mild to severe, or life-threatening and can vary from person to person. However, adequate safety measures will be in place to reduce the risk of severe unwanted effects happening. During this study, participants will have regular check-ups to see if there are any unwanted effects.

RO7504109:
RO7504109 is currently being tested in humans. Not all the unwanted effects of this medicine are known at this time. Participants will be told about the possible unwanted effects based on laboratory studies or knowledge of similar medicines. Known unwanted effects include low blood pressure, headache, and/or vomiting. Study medicine will be given as an injection or as an infusion, and the known unwanted effects are injection site pain and/or rash. The study medicine (s) may be harmful to an unborn baby. Women and men must take precautions to avoid exposing an unborn baby to the study treatment.

Where is the study run from?
F. Hoffmann-La Roche Ltd (Switzerland)

When is the study starting and how long is it expected to run for?
April 2024 to June 2026

Who is funding the study?
F. Hoffmann-La Roche Ltd (Switzerland)

Who is the main contact?
global.trial_information@roche.com

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Clinical Trials

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
BP45135

Study information

Scientific Title
A phase I, randomized, investigator/participant blind, parallel-group, placebo-controlled, single and multiple ascending dose study to determine the safety, tolerability, pharmacokinetics, and pharmacodynamics of RO7504109 in healthy participants

Study objectives
The main purpose of this study is to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of single and multiple ascending doses of intravenously (IV) and subcutaneously (SC) administered RO7504109 in healthy participants.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 06/05/2024, New Zealand Central Health and Disability Ethics Committee (Ministry of Health, 133 Molesworth Street, PO Box 5013, Wellington, 6011, New Zealand; 0800 400 569; hdecs@health.govt.nz), ref: 2024 FULL 19999

Study design
Randomized investigator/participant-blind parallel-group placebo-controlled single- and multiple-ascending-dose phase I study

Primary study design

Interventional

Study type(s)
Other, Treatment, Safety

Health condition(s) or problem(s) studied
Healthy volunteers

Interventions
Current interventions as of 11/03/2025:

Single Ascending Dose (SAD) part: Participants will receive a single dose of RO7504109 or a matching placebo, as IV infusion or SC injection, on Day 1.

Multiple Ascending Dose (MAD) part: Participants will receive multiple doses of RO7504109 or matching placebo, as IV infusion or SC injection, Q2W up to Day 57.

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Previous interventions:

Single Ascending Dose (SAD) part: Participants will receive a single dose of RO7504109 or a matching placebo, as IV infusion or SC injection, on Day 1.

Multiple Ascending Dose (MAD) part: Participants will receive multiple doses of RO7504109 or matching placebo, as IV infusion or SC injection, once every two weeks (Q2W) up to Day 57.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
RO7504109

Primary outcome(s)
Current primary outcome measure as of 11/03/2025:

1. SAD part and MAD part: Number of participants with adverse events (AEs) and severity of AEs graded according to the National Cancer Institute common terminology criteria for adverse events version 5.0 (NCI CTCAE v5.0) up to 155 days for the SAD part and up to 211 days for the MAD part
2. SAD part and MAD part: Number of participants with dose-limiting adverse events (DLAEs) as assessed and recorded by the investigator on the electronic case report form (eCRF) from Day 1 up to Day 15 for the SAD part and from Day 1 up to Day 44 for the MAD part
3. SAD Part and MAD Part: RO7504109 serum concentration after single or multiple IV or SC doses assessed using validated assays at multiple time points on Day 1 up to Day 155 for the SAD part and multiple time points on Day 1, up to Day 211 for the MAD part
4. SAD part: Dose proportionality of RO7504109 measured using the linear model at multiple time points on Day 1 up to Day 155

5. MAD part: Dose proportionality of RO7504109 measured using linear mixed effect model assessed at multiple time points on Day 1 up to Day 211
6. MAD part: Accumulation index after multiple IV or SC doses of RO7504109 measured using linear mixed effect model assessed at multiple time points on Day 1 up to Day 57
7. SAD part and MAD part: Area under the plasma concentration (AUC) curve of RO7504109 measured using standard non-compartmental methods at multiple time points on Day 1 up to Day 155 for the SAD part and multiple time points on Day 1 up to Day 211 for the MAD part
8. MAD part: Minimum plasma concentration (Cmin) of RO7504109 measured using standard non-compartmental methods at multiple time points on Day 1 up to Day 211 for the MAD part
9. SAD part and MAD part: Maximum plasma concentration (Cmax) of RO7504109 measured using standard non-compartmental methods at multiple time points on Day 1 up to Day 155 for the SAD part and multiple time points on Day 1 up to Day 211 for the MAD part
10. SAD part and MAD part: Clearance (CL) of RO7504109 measured using standard non-compartmental methods at multiple time points on Day 1 up to Day 155 for the SAD part and multiple time points on Day 1 up to Day 211 for the MAD part
11. SAD and MAD part: Volume of distribution at steady-state conditions (Vss) of RO7504109 measured using standard non-compartmental methods at multiple time points on Day 1 up to Day 155 for the SAD part and multiple time points on Day 1 up to Day 211 for the MAD part

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Previous primary outcome measure:

1. SAD part and MAD part: Number of participants with dose-limiting adverse events (DLAEs) as assessed and recorded by the investigator on the electronic case report form (eCRF) from Day 1 up to Day 15 for the SAD IV part, Day 1 up to Day 7 for the SAD SC part, and from Day 1 up to Day 31 for the MAD part
2. SAD part and MAD part: Number of participants with adverse events (AEs) and severity of AEs graded according to the National Cancer Institute common terminology criteria for adverse events version 5.0 (NCI CTCAE v5.0) from Screening up to 155 days for the SAD part and from Screening up to 211 days for the MAD part
3. SAD Part and MAD Part: RO7504109 serum concentration after single or multiple IV or SC doses assessed using validated assays at multiple time points on Day 1 up to Day 155 for the SAD part and multiple time points on Day 1, up to Day 211 for the MAD part
4. SAD part: Dose proportionality of RO7504109 measured using the linear model at multiple time points on Day 1 up to Day 155
5. MAD part: Dose proportionality of RO7504109 measured using linear mixed effect model assessed at multiple time points on Day 1 up to Day 211
6. MAD part: Accumulation index after multiple IV or SC doses of RO7504109 measured using linear mixed effect model assessed at multiple time points on Day 1 up to Day 57
7. SAD part and MAD part: Area under the plasma concentration (AUC) curve of RO7504109 measured using standard non-compartmental methods at multiple time points on Day 1 up to Day 155 for the SAD part and multiple time points on Day 1 up to Day 211 for the MAD part
8. MAD part: Minimum plasma concentration (Cmin) of RO7504109 measured using standard non-compartmental methods at multiple time points on Day 1 up to Day 211 for the MAD part
9. SAD part and MAD part: Maximum plasma concentration (Cmax) of RO7504109 measured using standard non-compartmental methods at multiple time points on Day 1 up to Day 155 for the SAD part and multiple time points on Day 1 up to Day 211 for the MAD part
10. SAD part and MAD part: Clearance (CL) of RO7504109 measured using standard non-compartmental methods at multiple time points on Day 1 up to Day 155 for the SAD part and multiple time points on Day 1 up to Day 211 for the MAD part
11. MAD part: Volume of distribution at steady-state conditions (Vss) of RO7504109 measured

using standard non-compartmental methods at multiple time points on Day 1 up to Day 155 for the SAD part and multiple time points on Day 1 up to Day 211 for the MAD part

Key secondary outcome(s))
There are no secondary endpoints

Completion date
30/06/2026

Eligibility

Key inclusion criteria
1. Healthy participants with body mass index (BMI) of 18 to 32 kilograms per metre squared (kg /m2) inclusive and a body weight of ≥50 kg at Screening.
2. Female participants of childbearing potential (POCBP) are eligible to participate if not pregnant, not breastfeeding, and agree to remain abstinent (refrain from heterosexual intercourse) or use at least one highly effective contraceptive method during the treatment period.
3. Male Participants must, during the treatment period at least 90 days after the last dose of study treatment, agree to remain abstinent (refrain from heterosexual intercourse) or use contraceptive measures.
4. Participants who are overtly healthy determined by no clinically significant findings from medical history, 12-lead electrocardiogram (ECG), or vital signs.

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Key exclusion criteria
Current exclusion criteria as of 11/03/2025:

1. History of any clinically significant gastrointestinal, renal, hepatic, bronchopulmonary, neurological, psychiatric, cardiovascular, endocrinological, hematological, or allergic disease (including stable asthma and childhood asthma), metabolic disorder, cancer (within the last 5 years), or cirrhosis.
2. History of tuberculosis or a positive QuantiFERON Gold test.

3. Any suspicion or history of alcohol abuse and/or suspicion of regular consumption of drugs of abuse.
4. Positive test (positive antibody or antigen confirmed with positive polymerase chain reaction [PCR]) result for hepatitis B virus (HBV), hepatitis C virus (HCV), or human immunodeficient virus (HIV) 1 and 2.
5. Positive test result (positive immunoglobulin [Ig]G and IgM) for cytomegalovirus or Epstein-Barr virus unless documented resolution of the disease.
6. Clinically significant joint problems including but not limited to ongoing pain or swelling that in the opinion of the Investigator, pose an unacceptable risk to the participant in this study.

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Previous exclusion criteria:

1. History of any clinically significant gastrointestinal, renal, hepatic, bronchopulmonary, neurological, psychiatric, cardiovascular, endocrinological, hematological, or allergic disease (including stable asthma and childhood asthma), metabolic disorder, cancer, or cirrhosis.
2. History of tuberculosis or a positive QuantiFERON Gold test.
3. Any suspicion or history of alcohol abuse and/or suspicion of regular consumption of drugs of abuse.
4. Positive test (positive antibody or antigen confirmed with positive PCR) result for hepatitis B virus (HBV), hepatitis C virus (HCV), or human immunodeficient virus (HIV) 1 and 2.
5. Positive test result (positive immunoglobulin [Ig]G and IgM) for cytomegalovirus or Epstein-Barr virus unless documented resolution of the disease.

Date of first enrolment
18/06/2024

Date of final enrolment
15/11/2025

Locations

Countries of recruitment
New Zealand

Study participating centre
NZCR
Auckland
New Zealand
1010

Sponsor information

Organisation
F. Hoffmann-La Roche Ltd

Funder(s)

Funder type
Industry

Funder Name
F. Hoffmann-La Roche

Alternative Name(s)
Hoffman-La Roche, F. Hoffmann-La Roche Ltd.

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Switzerland

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to participant-level data not being a regulatory requirement.

IPD sharing plan summary
Not expected to be made available