

Healthy Volunteers

A single-and multiple-dose, open-label, Phase I study to investigate the safety, tolerability, pharmacokinetics, pharmacodynamics, and immunogenicity of subcutaneously administered RO7204239 in adult participants with high body weight

Trial Status
Recruiting

Trial Runs In
1 Country

Trial Identifier
BP45369

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 single-and multiple-dose, open-label, Phase I study to investigate the safety, tolerability, pharmacokinetics, pharmacodynamics, and immunogenicity of subcutaneously administered RO7204239 in adult participants with high body weight

Trial Summary:

A study to find out the safety, tolerability and processing of RO7204239 by the body, the effect of RO7204239 on the body in participants with high body weight

F. Hoffmann-La Roche Ltd
Sponsor

Phase I
Phase

BP45369
Trial Identifiers

Eligibility Criteria:

Gender
Both

Age
18 to 80 years of age

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Yes

Background and study aims:

Obesity is a complex health issue that occurs due to the accumulation of extra (surplus) body fat. This condition significantly increases the risk of developing other diseases and health issues, including heart disease, a group of health conditions that cause a person's blood sugar to become too high (diabetes) and high blood pressure.

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This study is testing a medicine called RO7204239. It is being developed as a possible treatment for obesity. RO7204239 is an experimental medicine. This means health authorities (like the U.S. Food and Drug Administration and European Medicines Agency) have not approved RO7204239 for the treatment of obesity. This study aims to test how safe RO7204239 is (at single and multiple doses), what happens once it is in the body, and what RO7204239 does to the body.

Who can participate?

People (males and females) aged 18-80 years with a body weight of at least 90 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 about 6 weeks before the start of the treatment.

Everyone who joins this study will be split into two groups to receive RO7204239 given as an injection under the skin. Participants in Group 1 will receive a single dose of RO7204239 on Day 1 and those in Group 2 will receive multiple doses of RO7204239 for about 12 weeks. Participants will have regular blood tests and will be checked for unwanted effects throughout the study.

This is an open-label study. This means everyone involved, including the participant and the study doctor, will know the study treatment the participant has been given.

During the study, the study doctors will see the participants 11 times (group 1) or 17 times (group 2) during the clinic visits. Study doctors will see how well the treatment is working and any unwanted effects participants may have. Participants will have 12 follow-up visits after completing the study treatment, during which the study doctor will check on the participant's well-being. The total time of participation in the study will be about 42 weeks for Group 1 and about 54 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?

Taking part in the study may or may not make participants feel better. However, the information collected in the study can help people with obesity in the future.

It may not be fully known at the time of the study how safe the study treatment is in healthy volunteers. The study involves some risks to the participant, but these risks are generally mild and easily monitored. People interested in taking part will be informed about the risks, as well as procedures or tests they may need to undergo. All details of the study will be

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described in an informed consent document. This includes information about possible side effects.

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, even life-threatening, and vary from person to person. During this study, participants will have regular check-ups to see if there are any unwanted effects.

Participants will be told about the known unwanted effects of RO7204239, and possible unwanted effects based on human and laboratory studies or knowledge of similar medicines. Known unwanted effects include local irritation, pain, swelling, hardening of the skin, itching, redness, and rash at the injection site.

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)

Who is funding the study?

F. Hoffmann-La Roche Ltd (Switzerland)

Who is the main contact?

global.trial_information@roche.com

Inclusion Criteria:

- Healthy participants (other than body weight-related conditions) as determined by medical evaluation including medical history, physical examination, laboratory tests, and cardiac monitoring
- Body weight ≥ 90 kilograms (kg) and body mass index (BMI) ≥ 25 kilograms per square meter (kg/m²)
- Must agree to refrain from starting a significant new exercise routine or major change to a previous exercise/diet routine within 4 weeks before screening and to maintain their level of physical activity consistently through study Day 113

Exclusion Criteria:

- Presence of clinically significant cardiovascular disease (e.g., cardiac insufficiency, unstable angina, cardiomyopathy, congestive heart failure, or valve disorders or defects)
- Significant allergies to humanized monoclonal antibodies (mAbs)
- Lymphoma, leukemia, or any malignancy within the past 5 years
- Breast cancer within the past 10 years

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- Current or chronic history of liver disease or known hepatic or biliary abnormalities
- Gastric bypass surgery
- Any abnormal skin conditions or potentially obscuring pigmentation or lesions in the area intended for SC injection that would prevent visualization of potential injection site reactions (ISRs) to RO7204239
- Use of anti-obesity medications within 6 months prior to enrollment
- Live vaccine(s) within one month before screening or plans to receive live vaccines during the study or within 28 days of the last study treatment administration
- Treatment with biologic agents (such as mAbs including marketed drugs) within 3 months or five half-lives (whichever is longer) prior to dosing
- Presence of hepatitis B surface antigen and/or total hepatitis B core antibody, a positive hepatitis C or human immunodeficiency virus (HIV) antibody test result, and/or evidence of HIV infection at Screening or within 3 months prior to first study treatment administration