ForPatients
by Roche

ObesityType 2 Diabetes Mellitus

A study to look at how RO7204239 works to reduce certain signs of type 2 diabetes mellitus

A Study to Evaluate the Effect of RO7204239 on Insulin Sensitivity and Muscle Composition in Participants With Type 2 Diabetes Mellitus (T2DM) and Overweight or Obesity

Trial Status	Trial Runs In	Trial Identifier
Not yet recruiting		NCT07137585 2025-521401-41-00 BP45980

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:

Effects of RO7204239 on Insulin Sensitivity, Muscle Composition and Function in Participants Living With Type 2 Diabetes Mellitus and Overweight or Obesity: A Double-blind, Randomized, Placebo-controlled Study

Trial Summary:

The main purpose of this study is to assess the effect of RO7204239 on insulin sensitivity versus placebo in participants with T2DM and obesity or overweight.

Hoffmann-La Roche Sponsor	**Phase 1** Phase

NCT07137585 2025-521401-41-00 BP45980
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

1. WHY IS THIS STUDY NEEDED?

This study is testing a medicine called RO7204239. Treatment with RO7204239 alongside diet modification and exercise might lead to improved insulin sensitivity and weight loss.

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 people who have type 2 diabetes mellitus and are overweight or obese. Diabetes mellitus is a group of health conditions that cause a person's blood sugar to become too high. This happens when the body does not make enough insulin or does not respond to insulin the way it should.

The aim of this study is to compare the effects of RO7204239 versus a placebo on blood sugar control in people living with type 2 diabetes mellitus who are overweight or obese. Other aims are to see how RO7204239 works, how it gets to different parts of the body, and how the body gets rid of it. Participants in this study will get either RO7204239 or placebo. A placebo is a drug that contains no active ingredients but looks the same and is taken in the same way as the study medicine. Insulin is a molecule in the body that turns food into energy and controls the level of sugar in the blood.

2. WHO CAN TAKE PART IN THE STUDY?

People aged 18 years and above can take part in the study if they have type 2 diabetes mellitus for at least 6 months and a body mass index of # 27 to # 45 kg/m 2.

People may not be able to take part in this study if they have a history of any medical condition capable of creating a risk when taking the study medication.

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

3. HOW DOES THIS STUDY WORK?

Participants will be screened to check if they are able to participate in the study. The screening and pre-treatment period with 2 visits to the study doctor will take place from 4 weeks to 3 days before the start of treatment.

Everyone who joins this study will be split up into one of 2 groups randomly (like throwing a dice). They will receive either RO7204239 or placebo depending to which group they are assigned. RO7204239 or placebo will be injected under the skin in the belly very 4 weeks for 24 weeks. Two thirds of the participants will receive RO7204239 and one third will receive placebo.

This is a ‘placebo-controlled’ study. This means that participants are put in a group that will receive a medicine or a group that will receive ‘placebo’ (a medicine that contains no active ingredients but looks the same and is taken in the same way as the study medicine). Comparing results from the different groups helps researchers know if any changes seen result from the study medicine or occur by chance.

This is a double-blinded study. This means that neither the participants in the study nor the team running it will know which treatment is being given until the study is over. This is done to make sure that the results of the treatment are not affected by what people expected from the received treatment. However, the study doctor can find out which group the participant is in, if the participants' safety is at risk.

During the first 6 months of this study, the study doctor will see participants for treatment every 4 weeks. Each visit may be from several hours to 3 days (with 2 nights in clinic). The duration of a visit depends on the assessments, tests, and procedures that are needed to see how well the treatment is working and any unwanted effects participants may have. Participants will have one follow-up visit after 6 months of completing the study treatment, during which the study doctor will check on the participant’s well-being. Total time of participation in the study will be about 1 year. Participants have the right to stop study treatment and leave the study at any time, if they wish to do so.

4. WHAT ARE THE MAIN RESULTS MEASURED IN THIS STUDY?

The main result obtained from the study assessments is the change in insulin sensitivity (e.g., how well the body responds to insulin) after 24 weeks of receiving RO7204239 or placebo.

Other key results measured in the study after 12 and 24 weeks of treatment include:

- Changes in various indicators of how the body processes sugar
- The exact amount of weight gained or lost in kilograms
- Changes in body mass index and waist circumference
- Changes in total amount of fat and lean (non-fat) tissue in the body, using magnetic resonance imaging (MRI) scans; MRI scan is a detailed picture of the inside of the body taken with a special machine.
- Changes in the volume of muscles and fat within muscles using MRI
- Assess the safety and tolerability of RO7204239

5. ARE THERE ANY RISKS OR BENEFITS IN TAKING PART IN THIS STUDY?

Taking part in the study may or may not make participants feel better. But the information collected in the study can help other people with similar health conditions in the future.

It may not be fully known at the time of the study how safe and how well the study treatment works. The study involves some risks to the participant. But these risks are generally not greater than those related to routine medical care or the natural progression of the health condition. People interested in taking part will be informed about the risks and benefits, 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 effects and other options of treatment.

Risks associated with the study drugs and procedures Participants may experience unwanted effects from the drugs and procedures 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.

RO7204239 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 and pain or swelling at the injection site. Possible unwanted effects include allergic type reactions, and muscle twitching or muscle spasms.

RO7204239 or placebo will be given as an injection under the skin in the belly).

The study medicine(s) may be harmful to an unborn baby. Women and men must take precautions to avoid becoming pregnant (women), fathering a child (men) and exposing an unborn baby to the study treatment.

Inclusion Criteria:

- Participants with T2DM for at least 6 months, treated with diet, exercise and/or metformin alone or in combination with either dipeptidyl peptidase 4 (DPP-4) inhibitor or sodium-glucose co-transporter 2 (SGLT2) at stable dose for the last 3 months prior to study entry and with a HbA1c between # 6.5% and # 10%
- Body mass index (BMI) within the range of 27.0 to 45.0 kilogram per meter square (kg/m2)
- Stable body weight for the 3 months prior to screening
- Participants on lipid-lowering or antihypertensive drugs must be on stable doses for at least 3 months

Exclusion Criteria:

- Type 1 diabetes mellitus (DM), known latent autoimmune diabetes in adults, or people with an episode of ketoacidosis or hyperosmolar state requiring hospitalisation in 6 months prior to screening
- Active proliferative diabetic retinopathy, diabetic maculopathy, or severe non-proliferative diabetic retinopathy requiring acute treatment
- Uncontrolled comorbid conditions commonly associated with diabetes (for example, hypertension, hyperlipidaemia)
- Severe hypoglycaemia within 6 months prior to screening visit
- Current autonomic neuropathy as evidenced by neuropathic urinary retention, resting tachycardia, orthostatic hypotension, or diabetic diarrhea
- Have evidence of a significant, uncontrolled endocrine abnormality (e.g., thyrotoxicosis and adrenal crises)
- Are currently taking a central nervous system stimulant (e.g., Ritalin-SR), with the exception of caffeinated beverage
- Have a known allergy, hypersensitivity, or intolerance to any component of the study treatment (i.e., RO7204239 / placebo) formulation
- Blood donation of more than 500 milliliters (mL) within the past 3 months or blood transfusion or severe blood loss within 3 months prior to screening