ForPatients
by Roche

ObesityType 2 Diabetes Mellitus

A clinical study to evaluate the effects of RO7795068 in participants with obesity or overweight and type 2 diabetes.

A Clinical Study to Evaluate the Effects of Enicepatide (RO7795068) in Participants With Obesity or Overweight and Type 2 Diabetes

Trial Status	Trial Runs In	Trial Identifier
Recruiting	22 Countries	NCT07351058 2025-523106-32-00 2025 WC45726

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 phase III, randomized, double-blind, placebo-controlled, parallel group study to evaluate the efficacy and safety of once-weekly RO7795068 administered to participants with obesity or overweight and type 2 diabetes

Trial Summary:

The purpose of this study is to assess the efficacy and safety of enicepatide, a dual glucagon-like peptide-1 (GLP-1)/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (RA), at multiple doses compared with placebo for weight management in participants with obesity or overweight and Type 2 diabetes mellitus (T2DM).

Hoffmann-La Roche	Phase 3
Sponsor	Phase

NCT07351058 2025-523106-32-00 2025 WC45726
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

1. Why is this study needed?

Obesity is a complex, long-term medical condition that can lead to various health problems, including issues with physical function and mental health. Many different

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factors contribute to obesity, such as genetics, biology, the environment a person lives in, and their socio-economic situation. Obesity or overweight and type 2 diabetes (T2DM) are closely connected. T2DM is a condition where blood sugar stays too high because the body does not make enough insulin or cannot use it properly. Living with obesity or overweight can make T2DM harder to manage, while losing weight can help improve T2DM. There is still a need for treatment options that help people achieve a healthier weight and better blood sugar control.

This study is testing a medicine called RO7795068. It is being developed to treat obesity or overweight in people who live with T2DM.

RO7795068 is an experimental medicine. This means health authorities (like the U.S. Food and Drug Administration and European Medicines Agency) have not approved RO7795068 for the treatment of obesity or overweight.

This study aims to compare the effects of RO7795068 against non-active medicine (placebo) in people living with obesity or overweight and T2DM.

2. Who can take part in the study?

People (male / female) can take part in the study if they are 18 years or older and have T2DM along with obesity or overweight. In this study, a person is considered living with overweight or obesity if they have a body mass index (BMI), of 27 kg/m² or higher. BMI is a measure used to assess whether a person's weight is healthy for their height.

People may not be able to take part in this study if they have severe T2DM-related health problems, have experienced severe low blood sugar in the last 6 months, or use injectable T2DM treatment. People who have recently gained or lost a lot of weight (more than 5 kg in the last 3 months) or who have received certain weight loss treatments in the last 6 months will also not be able to take part. People who are pregnant, planning to get pregnant, or currently breastfeeding cannot take part in the study.

3. How does this study work?

People will be screened to check if they are able to participate in the study. The screening period will take place for about 4 weeks before the start of treatment.

Everyone who joins this study will be randomly split up into 4 groups of about the same size (like rolling a die) and self-administer either:

1. Non-active medicine (placebo), given as an injection under the skin (subcutaneous injection), once every week for 72 weeks
2. RO7795068 (low dose), given as an injection under the skin, once every week for 72 weeks

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3. RO7795068 (medium dose), given as an injection under the skin, once every week for 72 weeks
4. RO7795068 (high dose), given as an injection under the skin, once every week for 72 weeks

Participants will have an equal chance of being placed in any of the 4 groups.

This is a ‘placebo-controlled’ study. This means that participants are put in a group that will receive an active 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 expect from the treatment they receive. However, the study doctor can find out which group a participant is in, if the participants' safety is at risk.

During this study, the study doctor will see participants every 4 weeks for the first 36 weeks and then every 12 weeks thereafter. They will perform assessments to understand how well the treatment is working and note any unwanted effects participants may have. After completing the main treatment period, all participants will have the option to take part in an extension of the study. Participants will have 1 follow-up visit 4 weeks after their last dose, during which the study doctor will check on the participants and look for any unwanted effects. The total time of participation in the study will be about 1.5 years. 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 results measured in the study to assess if the medicine has worked are the percentage change in the body weight from the start of the study to week 72. Other key results measured in the study include:

- The number of participants who achieve various levels of weight loss (5%, 10%, and 15%) by week 72
- Changes in body weight (in kilograms) by week 72
- Changes in waist size by week 72
- Changes in measures related to T2DM including HbA1c (average blood sugar over the past 2–3 months), fasting glucose, and insulin by week 72
- Changes in measures related to the heart (cholesterol, triglycerides, and blood pressure), and ability to do daily activities by week 72

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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 may 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 medicine
Participants may have unwanted effects from the medicine 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.

RO7795068 has had limited testing in humans. Therefore, the unwanted effects of this medicine are not known now. Participants will be told about the possible unwanted effects based on laboratory studies or knowledge of similar medicines. Possible unwanted effects include wanting to throw up, throwing up, loose, watery [and more frequent] stools, inflammation of pancreas, gall bladder and/or bile ducts and low blood sugar levels.

RO7795068 and placebo will be self-administered as an injection under the skin. Known unwanted effects of injection include reactions at the injection site, such as bruising (dark purple or blackish in colour), swelling, and itching.

The study medicine(s) may be harmful to an unborn baby. Women must take precautions to avoid exposing an unborn baby to the study treatment.

Inclusion Criteria:

- Ability and willingness to self-administer the study drug (or receive an injection from a trained individual if visually impaired or with physical limitations)
- Diagnosis of type 2 diabetes mellitus (T2DM) according to WHO classification or other locally applicable standards with HbA1c #6.5% to #10% determined by laboratory test at screening, and on stable oral therapy for at least 3 months prior to screening (if applicable). T2DM may be treated with diet/exercise alone or any oral anti-hyperglycemic medication (as per local labeling) EXCEPT dipeptidyl peptidase 4 (DPP-4) inhibitors or GLP-1 RA-based therapy.
- Body mass index (BMI) #27.0 kg/m^2
- History of #1 self-reported unsuccessful diet/exercise effort to lose body weight

Exclusion Criteria:

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- History of type 1 diabetes mellitus (T1DM) or any lifetime history of ketoacidosis or history of hyperosmolar state/coma within 12 months prior to screening
- Have had 1 or more episodes of severe hypoglycemia and/or has hypoglycemia unawareness within the 6 months prior to screening
- At least 2 confirmed fasting blood glucose values >270 mg/dL (15.0 mmol/L) (on 2 non-consecutive days) during screening
- Self-reported change in body weight >5 kg within 3 months prior to screening
- Obesity induced by other endocrinologic disorders (e.g., Cushing's syndrome) or diagnosed monogenetic or syndromic forms of obesity (e.g., melanocortin 4 receptor deficiency or Prader-Willi syndrome)
- Prior or planned surgical treatment for obesity. Liposuction or abdominoplasty if performed more than 1 year prior to screening is allowed.
- Known clinically significant gastric emptying abnormality (e.g., severe gastroparesis or gastric outlet obstruction)
- Poorly controlled hypertension at screening
- Have any of the following cardiovascular conditions within 3 months prior to screening: Acute myocardial infarction; Cerebrovascular accident (stroke)/transient ischemic attack; Unstable angina; Hospitalization due to congestive heart failure
- Treatment with any approved or investigational GLP-1-RA-based therapy (e.g., GLP-1 receptor mono agonist, GLP-1/GIP receptor dual agonist, GLP-1/GIP/Gluc receptor triple agonist) within 6 months prior to randomization

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