ForPatients
by Roche

ObesityType 2 Diabetes Mellitus

A study of CT-388 in participants living with obesity or overweight and Type 2 diabetes

A Study of CT-388 in Participants Who Are Overweight or Obese with Type 2 Diabetes Mellitus

Trial Status	Trial Runs In	Trial Identifier
Completed	6 Countries	NCT06628362 XC45544 CT-388-104

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 Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multi-Center Phase 2 Study to Evaluate the Efficacy, Safety, and Tolerability of Once-Weekly CT-388 Administered Subcutaneously for 48 Weeks to Participants Who Are Overweight or Obese With Type 2 Diabetes Mellitus

Trial Summary:

This is a multi-center, randomized, double-blind, placebo-controlled, parallel group dose-finding study to evaluate the efficacy and safety of enicepatide at low, middle, and high doses in participants who are overweight or obese with Type 2 diabetes mellitus (T2DM).

Carmot Therapeutics, Inc.	Phase 2
Sponsor	Phase

NCT06628362 XC45544 CT-388-104
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years & # 75 Years	No

1. Why is this study needed?

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 (called ‘Type 1 diabetes’) or does not respond to insulin the way it should (called ‘Type 2

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diabetes). Insulin is a molecule in the body that turns food into energy and controls the level of sugar in the blood.

People who are living with obesity or overweight are at higher risk of developing health issues. These include Type 2 diabetes and problems that affect the heart and the blood vessels (cardiovascular disease). People with obesity have a body mass index (BMI) of at least 30kg/m2, and those living overweight have a BMI of at least 25kg/m2. Weight loss can improve health, reduce the risk or seriousness of other health problems, or even reverse the symptoms of Type 2 diabetes. But it can be difficult to lose enough weight through diet and exercise alone. People usually need to lose around 15% of their body weight to improve a weight-related health issue, such as Type 2 diabetes. New medicines to support weight management are needed.

This study is testing a medicine called CT-388. It is being developed to treat people living with obesity or overweight with or without Type 2 diabetes. CT-388 is an experimental medicine. This means health authorities (like the U.S. Food and Drug Administration and European Medicines Agency) have not approved CT-388 for weight management or for treating Type 2 diabetes.

This study aims to compare the effects of CT-388 against ‘placebo’ (a medicine that contains no active ingredients but looks the same and is taken in the same way as the study medicine) in people living with obesity or overweight and have Type 2 diabetes.

2. Who can take part in the study?

People of 18 to 75 years of age with obesity or overweight can take part in the study if they have been diagnosed with Type 2 diabetes at least 6 months before starting the study. They must also have tried to lose weight through diet and exercise but were not successful.

People may not be able to take part in this study if they have certain other medical conditions including Type 1 diabetes, or have had specific treatments, including weight-loss medicines (such as liraglutide or semaglutide) within the last 6 months. People who are pregnant, breastfeeding or planning to become pregnant during the study or within 6 weeks of finishing the study treatment 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 up to 5 weeks before the start of treatment.

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. Comparing results from

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the different groups helps researchers know if any changes seen result from the study medicine or occur by chance.

Everyone who joins this study will be placed into 1 of 5 groups and given either different doses of CT-388, OR placebo. All treatment will be given as an injection under the skin (subcutaneous injection) once a week.

Participants will have a 4 in 5 chance (80%) of being placed in a CT-388 dose group and a 1 in 5 chance (20%) of being placed in the placebo group.

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 this study, the study doctor will see participants at least every 4 weeks. They will see how well the treatment is working and any unwanted effects participants may have. Participants will also visit the study centre every week to be given the study treatment, or a nurse may give treatment in the participant’s home. Participants will have a follow-up visit 5 weeks after completing the study treatment, or 1 week after their last dose if they decide to stop the study treatment, during which the study doctor will check on the participant’s wellbeing. 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 results measured in the study to assess if the medicine has worked are change in body weight and change in blood sugar levels (known as ‘HbA1c’) after about 11 months of study treatment.

Other key results measured in the study include:

- The number of participants with at least 5, 10, 15, 20, or 25% weight loss after 11 months
- The number of participants with blood sugar below 7% after 11 months
- Change in body weight after about 6 months
- Changes in blood sugar during the study, and how many participants have certain levels at specific times
- The number of participants with blood sugar below 7% with at least 5% weight loss, or blood sugar at or below 6.5% with at least 10% weight loss, at 6 and 11 months
- Change in body weight, BMI and waist and hip measurements after 11 months
- Changes in blood markers for how the body processes sugar

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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 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 CT-388 Participants may have unwanted effects of 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.

Participants will be told about the known unwanted effects of CT-388, and possible unwanted effects based on human and laboratory studies or knowledge of similar medicines. Known unwanted effects include wanting to throw up, throwing up, loose watery stools and feeling less hungry than usual. CT-388 and placebo will be given as a subcutaneous injection. Known unwanted effects include a reaction on the skin where it has been pricked with a needle to give a treatment, such as bruising, discomfort, swelling, or itching.

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.

Inclusion Criteria:

- Male or female, 18 to 75 years of age
- Body mass index (BMI) #25.0 kg/m^2
- Have a diagnosis of Type 2 Diabetes Mellitus (T2DM) according to the World Health Organization classification or other locally applicable standards
- Have an HbA1c #7% and #10.5%
- Management of T2DM with diet and exercise alone, metformin, or a sodium-glucose cotransporter-2 (SGLT-2) inhibitor, as monotherapy or in combination, per approved local label
- At least one self-reported unsuccessful diet/exercise effort to lose body weight

Exclusion Criteria:

- Have Type 1 Diabetes Mellitus (T1DM), history of ketosis or hyperosmolar state/coma, or any other types of diabetes except T2DM
- Have had 1 or more episodes of Level 3 hypoglycemia or have had hypoglycemia unawareness within 3 months prior to screening

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- Have history or presence of proliferative diabetic retinopathy, diabetic macular edema, or non-proliferative diabetic retinopathy that requires acute treatment
- Have evidence of clinically significant autonomic neuropathy (symptoms may include resting tachycardia, orthostatic hypotension, or diabetic diarrhea)
- Had treatment with any oral antihyperglycemic medications, with the exception of metformin or SGLT-2 inhibitors, within 3 months prior to screening or planned concurrent treatment with these medications during the study
- Had treatment with injectable antihyperglycemic medication, with the exception of short-term insulin, within 6 months prior to screening or planned concurrent treatment with these medications during the study
- Self-reported body weight change of >5 kg within 3 months before screening
- Any unbalanced/extreme diets, such as very low calorie, low carbohydrate, very high protein, ketogenic, or intermittent diets, within 3 months of the screening visit, or plan to be on such diets during the study
- Current or recent use of any treatment that promotes weight loss or glucose metabolism
- Current or recent use of treatment that may cause weight gain
- Prior or planned surgical treatment or procedure for obesity, except for liposuction or abdominoplasty if performed >1 year prior to screening. Participants with a history of devices, such as LAP-BAND® or intragastric balloon, are permitted, if devices were removed >1 year prior to screening.
- History of clinically significant or active gastric emptying abnormality (e.g., severe gastroparesis or gastric outlet obstruction, intestinal obstruction), or chronic use of medications that directly affect GI motility
- History of chronic pancreatitis or acute pancreatitis or have signs and symptoms of acute pancreatitis at screening
- Have obesity induced by other endocrinologic disorders (e.g., Cushing syndrome) or diagnosed monogenetic or syndromic forms of obesity
- History or diagnosis of significant active or unstable major depressive disorder or any history/diagnosis of other severe psychiatric conditions (e.g., schizophrenia; bipolar disorder; other serious mood disorder or anxiety disorder, or hyperactivity disorder) within the last year before screening
- History of any hematologic conditions that may interfere with HbA1c measurement (e.g., hemolytic anemias, sickle cell disease, other hemoglobinopathies)
- Family or personal history of medullary thyroid carcinoma
- Women who are pregnant, breastfeeding, or intend to become pregnant, or are of childbearing potential and not using a highly effective contraceptive method as required per protocol

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