ForPatients
by Roche

Obesity

A Study of CT-388 in Participants With Obesity or Overweight With at Least One Weight-Related Comorbidity

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	1 Country	NCT06525935 XC45526 CT-388-103

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 for 48 Weeks to Participants With Obesity or Overweight With at Least One Weight-Related Comorbidity

Trial Summary:

This is a multi-center, randomized, double-blind, placebo-controlled, parallel group dose-finding study to evaluate the efficacy and safety of CT-388 at low, middle, and high doses in participants with obesity or who are overweight with at least one weight-related comorbidity.

Carmot Therapeutics, Inc.
Sponsor

Phase 2
Phase

NCT06525935 XC45526 CT-388-103
Trial Identifiers

Eligibility Criteria:

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

Inclusion Criteria:

- Male or female, 18 to 75 years of age
- Body mass index (BMI) #30.0 kg/m2, OR BMI #27.0 and <30.0 kg/m2 and previously diagnosed with at least 1 of the following weight-related comorbidities, such as: prediabetes, hypertension, dyslipidemia, obstructive sleep apnea, or cardiovascular disease

- At least one self-reported unsuccessful effort to lose body weight

Exclusion Criteria:

- Prior history/diagnosis/lab evidence of any type of diabetes mellitus (e.g., Type 1, Type 2, gestational), or a history of ketoacidosis or hyperosmolar state
- Self-reported body weight change of >5 kg within 3 months before randomization
- Any unbalanced/extreme diets within 3 months of the screening visit, or plan to be on such diets during the study
- Current or recent participation in an organized weight reduction program
- 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 for obesity
- Clinically significant or active gastric emptying abnormality, malabsorption, or chronic use of medications that directly affect GI motility
- History of chronic pancreatitis or acute pancreatitis within 6 months before screening
- Have obesity induced by other endocrinologic disorders (e.g., Cushing syndrome) or diagnosed monogenetic or syndromic forms of obesity
- History of major depressive disorder within 2 years of screening, or any history/diagnosis of other severe psychiatric conditions (Note: Prospective participants with depression or anxiety whose disease state, in the opinion of the Investigator, is considered stable and expected to remain stable throughout the course of the study, may be considered for inclusion)
- Family or personal history of medullary thyroid carcinoma
- Serum calcitonin # 20 ng/L
- Women who are pregnant, breastfeeding, or intend to become pregnant, or are of childbearing potential and not using a highly effective contraceptive method