

Obesity

A Clinical Study to Evaluate the Effects of RO7795068 in Participants With Obesity or Overweight Without Type 2 Diabetes

Trial Status
Not yet recruiting

Trial Runs In

Trial Identifier
NCT07351045 2025-523104-71-00
WC45725

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 Without Type 2 Diabetes

Trial Summary:

The purpose of this study is to assess the efficacy and safety of RO7795068, 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 without Type 2 diabetes mellitus (T2DM) who have obesity or overweight with at least one weight-related comorbidity.

Hoffmann-La Roche
Sponsor

Phase 3
Phase

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Eligibility Criteria:

Gender
All

Age
#18 Years

Healthy Volunteers
No

Inclusion Criteria:

- Participants must have at screening:
- Body mass index (BMI) greater than or equal to (#)30.0 kg/m²; or

ForPatients

by Roche

- BMI ≥ 27.0 kg/m² and < 30.0 kg/m² with at least one weight-related comorbidity, such as prediabetes, hypertension, dyslipidemia, diagnosis of obstructive sleep apnea, or weight-related cardiovascular disease
- History of #1 self-reported unsuccessful diet/exercise effort to lose body weight
- Ability and willingness to self-administer the study drug (or receive an injection from a trained individual if visually impaired or with physical limitations)

Exclusion Criteria:

- History of Type 1 diabetes mellitus (T1DM) or T2DM, or history of ketoacidosis or hyperosmolar state/coma. Prior, but not current, diagnosis of gestational diabetes is allowed if no history of diabetes is recorded since.
- 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)
- History of acute or chronic pancreatitis or clinically significant gallbladder disease. History of acute pancreatitis caused by gallstones or clinically significant gallbladder disease is allowed if the participant had a cholecystectomy to resolve the problem at least 3 months prior to screening.
- Poorly controlled hypertension at screening
- 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.
- Have a history of significant active or unstable major depressive disorder (MDD) or other severe psychiatric disorder (e.g., schizophrenia, bipolar disorder, or other serious mood or anxiety disorder). Participants with MDD or generalized anxiety disorder whose disease state is considered stable within 1 year prior to screening and expected to remain stable throughout the course of the study, in the opinion of the investigator, are allowed provided that they are not receiving prohibited medication.
- 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