ForPatients
by Roche

Type 2 Diabetes Mellitus

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

Trial Status	Trial Runs In	Trial Identifier
Not yet recruiting		NCT07351058 2025-523106-32-00 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 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 with obesity or overweight and Type 2 diabetes mellitus (T2DM).

Hoffmann-La Roche
Sponsor

Phase 3
Phase

NCT07351058 2025-523106-32-00 WC45726
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

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:

- 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