

Obesity

A Study Evaluating the Effect of Daily Oral RO7795081 in Participants With Obesity or Overweight With at Least One Weight-Related Comorbidity

Trial Status
Recruiting

Trial Runs In
1 Country

Trial Identifier
NCT07081958 BP45702

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 II Study to Evaluate the Efficacy, Safety, and Tolerability of Once-Daily RO7795081 Administered for 38 Weeks to Participants With Obesity or Overweight With at Least One Weight-Related Comorbidity

Trial Summary:

This multicenter, randomized, double-blind, placebo-controlled, parallel-group, dose-range-finding, Phase II study aims to evaluate the efficacy, tolerability, and safety of RO7795081 for chronic weight management in adult participants with obesity or overweight with at least one weight-related comorbidity, but without diabetes mellitus.

Hoffmann-La Roche
Sponsor

Phase 2
Phase

NCT07081958 BP45702
Trial Identifiers

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 hypertension, dyslipidemia, diagnosis of obstructive sleep apnea, cardiovascular disease
- History of #1 self-reported unsuccessful diet/exercise effort to lose body weight
- A stable body weight for the 3 months prior to screening (maximum 5% body weight gain and/or loss)

Exclusion Criteria:

- Have a history or diagnosis of any type of diabetes mellitus (Type 1 diabetes [T1D], T2D, or rare forms of diabetes)
- Have 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)
- Participation in unbalanced/extreme diets or in an organized weight reduction program within 3 months of the screening visit or planning to engage in such diets or programs during the study
- Prior or planned surgical treatment for obesity
- Have a known, clinically significant gastric emptying abnormality
- Have poorly controlled hypertension, untreated renal artery stenosis, or evidence of labile blood pressure including symptomatic postural hypotension
- 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.
- Have a history of acute or chronic pancreatitis
- 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), or had a suicide attempt within the last 1 year of screening