ForPatients
by Roche

Obesity

A Study to Assess Efficacy, Safety, Tolerability, Pharmacokinetics (PK) and Pharmacodynamics (PD) of RO7204239 in Combination With Tirzepatide in Participants With Obesity or Overweight With At Least One Weight-related Comorbidity

Trial Status	Trial Runs In	Trial Identifier
Recruiting	4 Countries	NCT06965413 2024-519561-22-00 BC45538

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 Phase 2 Trial to Assess Efficacy, Safety, and Tolerability of RO7204239 in Combination With Tirzepatide in Participants With Obesity or Overweight With At Least One Weight-related Comorbidity

Trial Summary:

The main aim of the study is to assess the effect of RO7204239 in combination with tirzepatide, compared to placebo in combination with tirzepatide, on body weight loss after 48 weeks of treatment in adults with obesity or overweight with at least one weight-related comorbidity, but without diabetes mellitus (DM). The study comprises of a 4-week screening period; a 48-week core treatment period, where all participants will receive tirzepatide as background treatment and will be randomized to one of the 4 treatment arms; a 24-week treatment extension period, where participants will stop treatment with tirzepatide and a 24-week post-treatment follow-up (FU) period.

Hoffmann-La Roche	Phase 2
Sponsor	Phase

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Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- BMI # 30.0 kilograms per square meter (kg/m²) (additional weight-related comorbidities are not required for inclusion)
- BMI # 27.0 kg/m² and < 30.0 kg/m² with at least one weight-related comorbidity such as: hypertension, dyslipidemia, obstructive sleep apnea and any cardiovascular disease
- History of at least one self-reported unsuccessful dietary or exercise effort to lose body weight
- Weight stability: self-reported change in body weight less than 5 kilograms (kg) (11 pounds [lbs]) within 3 months prior to screening

Exclusion Criteria:

- Prior history or diagnosis of DM
- Presence of non-proliferative diabetic retinopathy requiring acute therapy, proliferative diabetic retinopathy or diabetic macular edema
- Have obesity induced by other endocrinologic disorders
- Participation in unbalanced/extreme diets
- Prior or planned surgical treatment for obesity
- Endoscopic and/or device-based therapy for obesity or device removal within 6 months prior to screening
- Have a known clinically significant gastric emptying abnormality
- Have any of the following cardiovascular conditions within 6 months prior to screening: acute myocardial infarction, cerebrovascular accident (stroke), unstable angina, or hospitalization due to congestive heart failure (CHF)
- Have evidence of significant active, uncontrolled cardiovascular, autoimmune, endocrine, renal, hepatic, dermatological, chronic respiratory or gastrointestinal disease, a neurological or psychiatric condition, or a history of any neuromuscular disorder or autoimmune/inflammatory disorders that may cause muscle wasting or medical condition capable of constituting a risk when taking the study medication or interfering with the interpretation of data, as judged by the investigator at screening
- Have evidence of a significant, uncontrolled endocrine abnormality
- Have a history of an active or untreated malignancy or are in remission from a clinically significant malignancy
- Have evidence of a significant, active autoimmune abnormality
- Have anemia
- Have signs and symptoms of any other liver disease other than nonalcoholic fatty liver disease
- Have an average weekly alcohol intake that exceeds 21 units per week (males) and 14 units per week (females)