

Obesity

A Dose-Finding Study of Petrelintide With Enicepatide (RO7795068) in Adults With Obesity or Overweight

Trial Status
Not yet recruiting

Trial Runs In

Trial Identifier
NCT07589686 CC46372

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 II, Randomized, Double-Blind, Placebo-Controlled, Dose-Finding Study to Evaluate the Efficacy and Safety of Petrelintide Co-Administered With RO7795068 in Adults With Obesity or Overweight

Trial Summary:

The main purpose of this study is to evaluate the safety and efficacy of the co-administration of petrelintide and enicepatide compared with placebo, petrelintide monotherapy, and enicepatide monotherapy in participants with obesity or overweight with at least one weight-related comorbidity.

Hoffmann-La Roche
Sponsor

Phase 2
Phase

NCT07589686 CC46372
Trial Identifiers

Eligibility Criteria:

Gender
All

Age
#18 Years

Healthy Volunteers
No

Inclusion Criteria:

- Male or female participants with Body Mass Index (BMI) # 30 kg/m² OR BMI # 27 kg/m² to < 30 kg/m² with at least one weight-related comorbidity
- History of at least one self-reported unsuccessful dietary effort to lose body weight

Exclusion Criteria:

ForPatients

by Roche

- HbA1c # 48 mmol/mol (6.5%) at screening
- History of Type 1 or Type 2 Diabetes
- Self-reported change in body weight > 5 kg within 90 days prior to screening
- Previous or planned obesity treatment with surgery (excluding liposuction, cryolipolysis, or abdominoplasty if performed > 1 year prior to or during screening)
- Previous or planned endoscopic and/or device-based obesity treatment or removal of device within the last 6 months prior to screening (e.g., mucosal ablation, gastric artery embolization, intragastric balloon and duodenal-jejunal endoluminal liner)
- Treatment with any GLP-1 receptor agonist, GLP-1/GIP receptor agonist (or any other GLP-1 based treatment) within 180 days prior to or during screening
- Current or previous treatment with petrelintide or any other amylin analog
- Obesity induced by Cushing syndrome or a diagnosis of monogenetic or syndromic forms of obesity
- History of severe psychiatric disorders
- History of any hematologic conditions that may interfere with HbA1c measurement
- Known history or presence of pancreatitis
- Known clinically significant gastric emptying abnormality or chronic treatment that affects GI motility
- New York Heart Association Functional Classification IV heart failure
- Pregnant or breastfeeding, or intending to become pregnant during the study or within the time frame in which contraception is required