ForPatients
by Roche

Type 2 Diabetes Mellitus

A Study to Compare Different Doses of RO7795081 With a Placebo or Semaglutide in People With Type 2 Diabetes

Trial Status	Trial Runs In	Trial Identifier
Recruiting	1 Country	NCT07112872 2024-520322-11-00 BP45703

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- and Open-Label Active Comparator- Controlled, Parallel-Group, Multi-Center Phase II Study to Evaluate the Efficacy, Safety, and Tolerability of Once-Daily RO7795081 Administered for 30 Weeks to Participants With Type 2 Diabetes Mellitus

Trial Summary:

This multicenter, randomized, double-blind, placebo- and open-label active comparator-controlled, parallel-group, dose-range-finding, Phase II study aims to evaluate the efficacy, tolerability, and safety of RO7795081 for glycemic control in adult participants with Type 2 diabetes mellitus (T2D).

Hoffmann-La Roche
Sponsor

Phase 2
Phase

NCT07112872 2024-520322-11-00 BP45703
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Have a diagnosis of Type 2 diabetes mellitus (T2D) for at least 6 months before screening
- Have an HbA1c #7% and #10.5% at screening
- Management of T2D with diet and exercise alone or with either a stable dose of metformin or/and sodium-glucose cotransporter-2 (SGLT-2) inhibitors

- Body mass index (BMI) #23.0 kg/m^2 at screening
- A stable body weight within 3 months prior to screening (maximum 5% self-reported body weight gain and/or loss)

Exclusion Criteria:

- Have Type 1 diabetes (T1D), history of ketosis or hyperosmolar state/coma, or any other types of diabetes except T2D
- Have had 1 or more episodes of Level 3 hypoglycemia or has hypoglycemia unawareness within the 6 months prior to screening
- History or presence of proliferative diabetic retinopathy, diabetic macular edema, or non-proliferative diabetic retinopathy that requires acute treatment
- Evidence of clinically significant/active nephropathy or neuropathy (including resting tachycardia, orthostatic hypotension, and diabetic diarrhea)
- Current treatment or treatment within 3 months of screening with any other anti-hyperglycemic medication except metformin or SGLT-2 inhibitors
- 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)
- Have a known, clinically significant gastric emptying abnormality
- Have poorly controlled hypertension at screening, 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