ForPatients
by Roche

Type 2 Diabetes Mellitus

A Clinical Study to Evaluate the Effects of Enicepatide Versus Tirzepatide in Participants With Type 2 Diabetes and Inadequate Blood Sugar Control on Oral Glucose-Lowering Medications

Trial Status	Trial Runs In	Trial Identifier
Not yet recruiting		NCT07889648 2026-526948-13-00 WC45975

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, Open-Label, Active-Controlled Study to Evaluate the Efficacy and Safety of Enicepatide Versus Tirzepatide Among Participants With Type 2 Diabetes and Inadequate Glycemic Control on Oral Glucose-Lowering Medications

Trial Summary:

The study will evaluate the efficacy and safety of enicepatide, a glucagon-like peptide-1/glucose-dependent insulinotropic polypeptide receptor (GLP-1/GIP) receptor agonist (RA), compared with tirzepatide among participants with type 2 diabetes mellitus (T2DM) and inadequate glycemic control on oral glucose-lowering medications.

Hoffmann-La Roche	Phase 3
Sponsor	Phase

NCT07889648 2026-526948-13-00 WC45975
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Have a diagnosis of type 2 diabetes mellitus (T2DM) based on World Health Organization (WHO) classification or other locally applicable diagnostic standards and have inadequate glycemic control in the opinion of the investigator

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- Have a HbA1c of #7.5% to #10.5% (or 58 millimole (mmol)/mol to 91 mmol/mol) at screening
- Receiving stable T2DM treatment with oral glucose-lowering medication, during the 90 days prior to screening, and throughout the screening period until randomization; Dose of oral glucose-lowering medication is considered stable if the dose was unchanged during this 90-day period
- Agree to not initiate a new diet, fast, and/or exercise program during the study which may result in changes in body weight or HbA1c, other than the standard of care lifestyle and dietary measures for diabetes treatment

Exclusion Criteria:

- History of type 1 diabetes mellitus (T1DM) diagnosis
- History of ketoacidosis or hyperosmolar state/coma within 12 months prior to screening
- One or more episodes of Level 3 hypoglycemia (per 2026 American Diabetes Association (ADA) Standards of Care in Diabetes) and/or one or more episodes of hypoglycemia unawareness within the 6 months prior to screening
- Self-reported change in body weight of more than 5 kilogram (kg) gain or loss within 90 days prior to screening
- Used any injectable glucose-lowering medication during the 90 days prior to screening, and throughout the screening period until randomization. Short term treatment with insulin for <14 days is permitted for necessary clinical situations
- Body Mass Index (BMI) <25.0 kg/square meter (m2) at screening
- Estimated glomerular filtration rate (eGFR) <15 milliliters per minute per 1.73 square meters (mL/min/1.73 m2)
- Treatment with any approved, investigational, compounded, or biosimilar versions of GLP-1 RA-based therapy (e.g., GLP-1 receptor agonist, GLP-1/GIP receptor agonist/antagonist, GLP-1/Glucagon receptor agonist, or GLP-1/GIP/Glucagon receptor agonist) or amylin analog within 6 months prior to randomization
- Prior non-response or intolerance to contemporary GLP-1 RA-based therapies

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