ForPatients
by Roche

Diabetic Retinopathy

A Study to Investigate the Safety, Tolerability, and Pharmacokinetics of RO7663498 Following Intravitreal Administration in Participants With Diabetic Retinopathy

Trial Status	Trial Runs In	Trial Identifier
Not yet recruiting		NCT07588100 BP46156

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 Multicenter, Non-Randomized, Open-Label, Multiple-Ascending-Dose Study to Investigate the Safety, Tolerability, and Pharmacokinetics of RO7663498 Following Intravitreal Administration in Participants With Diabetic Retinopathy

Trial Summary:

This study will assess the safety, tolerability, and pharmacokinetics (PK) of intravitreal (IVT) injections of RO7663498 in participants with diabetic retinopathy (DR).

Hoffmann-La Roche Sponsor	**Phase 1** Phase

NCT07588100 BP46156
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

General Inclusion Criteria

- Diagnosis of Diabetes Mellitus (DM) (Type 1 or Type 2), as defined by the World Health Organization and/or American Diabetes Association

Ocular Inclusion Criteria for the Study Eye

- BCVA score at screening of >= 19 letters in study eye using Early Treatment of Diabetic Retinopathy Study (ETDRS) visual acuity testing charts
- Non-proliferative diabetic retinopathy (NPDR) as assessed by the investigator and confirmed by the Central reading center (CRC)
- Collection of >= 90 micro liter (µL) AH deemed feasible and safe by the investigator.

Exclusion Criteria:

General Exclusion Criteria:

- Any known hypersensitivity to any of the following compounds: fluorescein; any dilating, anesthetic, or povidone iodine eye drops; or any excipients contained in the treatments used in this study.
- History of hypersensitivity to biologic agents, the investigational drug, or any of the excipients contained in the formulation administered IVT or systemically.

Ocular Exclusion Criteria for the Study Eye

- Center-involved Diabetic Macular Edema (DME)
- Any history or concurrent ocular conditions/procedures and/or visual system conditions of the below.
- Vitreoretinal surgery/pars plana vitrectomy.
- Any history of glaucoma surgery or planned glaucoma surgery during the study.
- Uncontrolled glaucoma
- Anterior segment neovascularization.
- Vitreous or preretinal hemorrhage.
- Any ocular disease other than DR and DME that may Confound assessment of the retina in the opinion of the investigator or Confound development of worsening DR, DME, or retinal nonperfusion.
- Any presence of active intraocular inflammation on Day 1 (i.e., Standardization of Uveitis Nomenclature [SUN] criteria > 0 or National Eye Institute [NEI] vitreous haze grading > 0) or any history of IOI.
- Aphakia or previous violation of the posterior capsule in the study eye

Ocular Exclusion Criteria for the Non-study Eye

- BCVA < 38 letters