ForPatients
by Roche

Diabetic Retinopathy

A Multicenter, Randomized Study in Participants With Diabetic Retinopathy Without Center-involved Diabetic Macular Edema To Evaluate the Efficacy, Safety, and Pharmacokinetics of Ranibizumab Delivered Via the Port Delivery System Relative to the Comparator Arm

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	2 Countries	NCT04503551 GR41675

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, Multicenter, Randomized Study of the Efficacy, Safety, and Pharmacokinetics of the Port Delivery System With Ranibizumab in Patients With Diabetic Retinopathy

Trial Summary:

Study GR41675 is a Multicenter, Randomized Study in Participants with Diabetic Retinopathy (DR) Without Center-Involved Diabetic Macular Edema (CI-DME) to Evaluate the Efficacy, Safety of the Port Delivery System with Ranibizumab (PDS) Relative to the Comparator Arm

Hoffmann-La Roche Sponsor	**Phase 3** Phase

NCT04503551 GR41675
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Age #18 years at time of signing Informed Consent Form

- Documented diagnosis of diabetes mellitus (Type 1 or Type 2)
- HbA1c level of #12% within 2 months prior to screening or at screening

Inclusion Criteria for Study Eye

- Moderately severe or severe NPDR (ETDRS-DRSS level 47 or 53)
- BCVA score of # 69 letters (20/40 approximate Snellen equivalent or better)

Exclusion Criteria:

- Uncontrolled blood pressure
- Cerebrovascular accident or myocardial infarction within 6 months prior to randomization
- Atrial fibrillation diagnosis or worsening within 6 months prior to randomization
- Current systemic treatment for a confirmed active systemic infection
- Renal failure requiring renal transplant, hemodialysis, or peritoneal dialysis, or anticipated to require hemodialysis or peritoneal dialysis at any time during the study
- History of other disease, other non-diabetic metabolic dysfunction, physical examination finding, or clinical laboratory finding giving reasonable suspicion of a condition that contraindicates the use of ranibizumab or surgical placement of the PDS implant; that might affect interpretation of the results of the study; or that renders the patient at high risk for treatment complications in the opinion of the investigator or Sponsor

Ocular Exclusion Criteria for Study Eye:

- Presence of center-involved diabetic macular edema (defined as CST #325 µm)
- Any intravitreal anti-VEGF treatment at any time prior to randomization
- Any use of medicated intraocular implants, including Ozurdex® or Iluvien® implants at any time prior to randomization
- Any intravitreal corticosteroid treatment at any time prior to randomization
- Any periocular (e.g., subtenon) corticosteroid treatment at any time prior to randomization
- Any PRP at any time prior to randomization
- Any macular laser photocoagulation (such as micropulse and focal or grid laser) at any time prior to randomization
- Active intraocular inflammation (grade trace or above)
- Clinically significant abnormalities of the vitreous-retinal interface involving the macular area or disrupting the macular architecture, such as vitreous-retinal traction or epiretinal membrane (assessed by the investigator and confirmed by the central reading center)
- Uncontrolled ocular hypertension or glaucoma and any such condition the investigator determines may require a glaucoma-filtering surgery during a participant's participation in the study
- History of glaucoma-filtering surgery, tube shunts, or microinvasive glaucoma surgery
- Any concurrent ocular condition (e.g., cataract, epiretinal membrane) that would require surgical intervention during the study to prevent or treat visual loss that might result from that condition
- Any concurrent ocular condition (e.g., amblyopia, strabismus) that may affect interpretation of study results
- History of other ocular diseases that gives reasonable suspicion of a disease or condition that contraindicates the use of ranibizumab, that might affect interpretation of study results, or that renders the participant at high risk for treatment complications

Ocular Exclusion Criteria for Either Eye

- Suspected or active ocular or periocular infection of either eye
- Any history uveitis including idiopathic, drug-associated or autoimmune-associated uveitis