ForPatients
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Diabetic Macular Edema

A Study to Evaluate Efficacy, Safety & Pharmacokinetics of the Port Delivery System (PDS) With Ranibizumab in Participants With Diabetic Macular Edema (DME) Compared With Intravitreal Ranibizumab; A Substudy to Evaluate the Safety of Re-implanting the PDS With Ranibizumab in Participants With DME (Pagoda)

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Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	1 Countries	NCT04108156 GR40550

The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

Trial Summary:

This study will evaluate the efficacy, safety, and Pharmacokinetics (PK) of the PDS with ranibizumab in participants with DME when treated every 24 weeks (Q24W) compared with intravitreal (IVT) ranibizumab 0.5 milligrams (mg) every 4 weeks (Q4W).

The substudy will evaluate safety of re-implanting the updated PDS with ranibizumab and the refill-exchange procedures following re-implantation in participants with DME who were previously enrolled in the main study, GR40550. Up to 100 participants from the main study will be enrolled and followed for a maximum of 72 weeks post-re-implantation in the substudy.

GR40550 Pagoda Re-Implantation Substudy Lay CTD December 2025.pdf

GR40550 Pagoda Re-Implantation Substudy Lay CTD December 2025_Spanish.pdf

Hoffmann-La Roche	Phase 3
Sponsor	Phase

NCT04108156 GR40550
Trial Identifiers

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Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years	No

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