ForPatients
by Roche

Macular EdemaAge-Related Macular Degeneration

A Study in Patients With Neovascular Age Related Macular Degeneration or Macular Edema Secondary To Retinal Vein Occlusion to Evaluate Usability of the Ranibizumab (Lucentis®) Prefilled Syringe (PFS)

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Country	NCT02698566 GX30020

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:

An Open-Label, Single-Arm Phase IIIb Study in Patients With Neovascular Age-Related Macular Degeneration or Macular Edema Secondary to Retinal Vein Occlusion to Evaluate the Usability of Lucentis® 0.5 mg Prefilled Syringe

Trial Summary:

This is a multicenter study designed to evaluate usability of ranibizumab PFS in patients with neovascular age related macular degeneration or macular edema secondary to retinal vein occlusion.

Genentech, Inc.	Phase 3
Sponsor	Phase

NCT02698566 GX30020
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	# 18 Years	No

Inclusion Criteria:

Ocular

- Study eye deemed to be indicated for ranibizumab ITV therapy at the discretion of the retina specialist

Exclusion Criteria:

Concurrent Ocular Conditions

- Patients legally blind in one or both eyes
- History of or any current clinically relevant intraocular inflammation or ocular inflammatory reaction (any grading from trace and greater is excluded), including non-infectious uveitis or uveitis, or sterile inflammatory reaction after the past ITV injections with any agent
- Active disorder of ocular adnexa and skin in the study eye, including ocular surface infections
- History of or any current indication of excessive bleeding and recurrent hemorrhages, including any prior excessive intraocular (including subconjunctival) bleeding or hemorrhages after ITV injection or intraocular procedures
- Uncontrolled intraocular pressure greater than (>) 25 millimeters of mercury (mmHg) in the study eye (uncontrolled means that it occurs even with intraocular pressure-lowering therapy)
- Use of therapies that are known to be toxic to any ocular tissues within the 6 months prior to enrollment

Prior Ocular Therapies

- Treatment with any ITV injection within the 27 days prior to Day 1
- Any invasive intraocular surgery, prior long-acting therapeutic agent, or ocular drug release device implantation (approved or investigational) in the study eye at any time during the past 3 months

General

- Receipt of any systemic (non-ocular) investigational drug within 3 months prior to Day 1
- Current systemic coagulation or bleeding disorders and history of recurrent hemorrhages
- Intolerance or known reaction to prior biological therapies
- History of other diseases or physical or laboratory examination findings that per the retina specialist represent a contraindication to ranibizumab use in the patient or may represent an unwarranted patient risk.
- Uncontrolled hypertension (systolic >160 mmHg and/or diastolic >100 mmHg while sitting)
- Current systemic infectious disease or a therapy for active infectious disease
- Pregnant or lactating