ForPatients
by Roche

Intraocular PressureGlaucoma

A Study of the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of RO7058584 Following 7 Days of Instillation of Eye Drops in Patients With Primary Open Angle Glaucoma or Ocular Hypertension

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Country	NCT03293992 BP39863

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 I, Multi-Center, Randomized, Adaptive, Investigator/Patient Masked, Multiple-Ascending Dose, Placebo and Active Comparator-Controlled Parallel Study to Investigate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of RO7058584 Following 7 Days of Topical Instillation of Eye Drops in Patients With Primary Open Angle Glaucoma or Ocular Hypertension

Trial Summary:

This is a Phase I, multi-center, randomized, adaptive, investigator/patient-masked, placebo-controlled, parallel multiple-ascending dose study (Part A) with an extension including up to two selected doses from Part A and latanoprost 0.005% as active comparator (Part B).

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

NCT03293992 BP39863
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	# 18 Years & # 90 Years	No

Inclusion Criteria:

- 18 to 90 years of age inclusive, at the time of signing the informed consent form

- Confirmed diagnosis of ocular hypertension (OHT) or primary open-angle glaucoma (POAG) in both eyes as determined by the investigator at screening
- Treatment-naïve participants or participants who are able to safely stop their Intraocular pressure (IOP)-lowering medication(s) prior to randomization according to the required minimum washout periods
- At baseline visit, IOP # 24 millimeters of mercury (mmHg) in the morning (8:00 AM ± 1h) and # 22 mmHg in the afternoon (2:00 PM ± 1h) measurement in the same eye and # 34 mmHg at all timepoints in both eyes
- Best corrected logarithm of the minimum angle of resolution (logMAR) visual acuity score of 0.7 or better in each eye as measured by Early Treatment Diabetic Retinopathy Study (ETDRS) visual acuity test at screening
- Central corneal thickness (pachymetry) measurement 450 to 620 micrometers (µm) in both eyes at screening
- Cup-to-disc ratio # 0.8 (both eyes) at screening
- Anterior chamber angle is open and non-occludable (both eyes) as confirmed by the investigator by gonioscopy examination at screening

Exclusion Criteria:

- Advanced visual field defects
- Other forms of glaucoma than POAG or OHT
- Any abnormality preventing reliable applanation tonometry
- Any clinically significant corneal scarring, haze or opacity
- Uncooperativeness of the participant that restricts adequate examination of IOP, ocular fundus or anterior chamber
- Any presence or history of uveitis or other history of any ocular inflammatory disease.
- History or signs of penetrating ocular trauma
- Risk of visual field or visual acuity worsening in either eye as a consequence of glaucoma progression or consequence of participation in the trial or any other ocular disease, according to the investigator's best judgment
- History of any glaucoma surgery
- History of refractive surgery
- Any other intra-ocular surgery within six months of screening
- Any active ocular disease requiring treatment.
- Use of any listed prohibited medications
- Current enrollment or past participation within the last 30 days before the screening visit in any other clinical study involving an investigational study treatment or any other type of medical research
- Any participant who is the investigator or any sub-investigator, research assistant, pharmacist, study coordinator, other staff thereof, directly involved in the conduct of the protocol