ForPatients
by Roche

Geographic Atrophy

The study of a new medicine (RO7303359) in people with a type of eye disease (geographic atrophy secondary to age-related macular degeneration)

A Study Evaluating the Safety, Tolerability, Pharmacokinetics, and Immunogenicity of Intravitreal Injections of RO7303359 in Participants With Geographic Atrophy Secondary to Age-related Macular Degeneration

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Country	NCT04615325 GR42163

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 1a, Multicenter, Open-label, Single-dose, Dose-escalation Study of the Safety, Tolerability, Pharmacokinetics, and Immunogenicity of Intravitreal Injections of RO7303359 in Patients With Geographic Atrophy Secondary to Age-related Macular Degeneration

Trial Summary:

This clinical trial was done to study a new medicine called, “RO7303359”, for the treatment of an eye disease: geographic atrophy secondary to age-related macular degeneration. Men and women at least 50 years old who had the eye disease and met other conditions could take part in this study. Researchers wanted to find out what the side effects of RO7303359 were. They also wanted to find the highest dose that people could tolerate.

Genentech, Inc. (A part of F. Hoffmann-La Roche Ltd., Switzerland)	Phase 1
Sponsor	Phase

NCT04615325 GR42163
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#50 Years	No

Inclusion Criteria:

Ocular Inclusion Criteria Study Eye:

- Visual acuity: BCVA letter score of 19-48 ETDRS letters (Snellen equivalent of 20/125-20/400) using ETDRS charts at a starting distance of 4 meters
- Well-demarcated area of GA secondary to AMD in the absence of choroidal neovascularization (CNV)
- GA area must be >/= 0.5 disc area (1.25 mm^2)

Exclusion Criteria:

Ocular Exclusion Criteria, Study Eye:

- GA in the study eye due to causes other than AMD
- History of vitrectomy surgery, submacular surgery, or other surgical intervention for AMD
- Previous laser photocoagulation for CNV, diabetic macular edema, retinal vein occlusion, or proliferative diabetic retinopathy
- Prior treatment with photodynamic therapy, external beam radiation therapy (for intraocular conditions), or transpupillary thermotherapy

Ocular Exclusion Criteria, Both eyes:

- Evidence of prior or active CNV
- Previous participation in interventional clinical trials for GA or dry AMD, except for vitamins and minerals, irrespective of the route of administration (i.e. ocular or systemic) within the last 6 months