

ForPatients

by Roche

Age-Related Macular DegenerationGeographic Atrophy

A study to look at how safe a study medicine was for patients – when taken at different doses - and how this medicine was processed through the body

Safety and Tolerability Study of RO7171009 in Participants With Geographic Atrophy (GA) Secondary to Age-Related Macular Degeneration (AMD)

Trial Status
Completed

Trial Runs In
1 Country

Trial Identifier
NCT03295877 GR39821

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, Multicenter, Open-Label, Single-Dose, Dose-Escalation, and Multiple-Dose Study of the Safety, Tolerability, Pharmacokinetics, and Immunogenicity of Intravitreal Injections of RO7171009 in Patients With Geographic Atrophy Secondary to Age-Related Macular Degeneration

Trial Summary:

This Phase 1, open-label, multicenter study will investigate the safety and tolerability of RO7171009 following single and multiple intravitreal (ITV) administrations in patients with GA secondary to AMD. The study consists of two stages: Single Dose-Escalation (SAD) and Multiple-Dose (MD) stages.

Genentech, Inc.
Sponsor

Phase 1
Phase

NCT03295877 GR39821
Trial Identifiers

Eligibility Criteria:

Gender
All

Age
50 Years

Healthy Volunteers
No

This was a study to investigate a new medicine (FHTR2163) in patients with an eye disease, called “age-related macular degeneration with geographic atrophy”, or “AMD with

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GA". Patients were injected in their eye with different amounts of the study medicine to find the dose that was safe.

Inclusion Criteria:

- Participants aged greater than or equal to (\geq) 50 years
- Well demarcated area(s) of GA secondary to AMD with no evidence of prior or active choroidal neovascularization (CNV) in study eye

Exclusion Criteria:

Ocular Exclusion Criteria, Study Eye:

- 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 Visudyne®, external beam radiation therapy (for intraocular conditions), or transpupillary thermotherapy

Ocular Exclusion Criteria (Both Eyes):

- GA in either eye due to causes other than AMD
- 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