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	Trial Runs In	Trial Identifier
Completed	1 Country	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	Age	Healthy Volunteers
All	# 50 Years	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

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 (>/=) 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