ForPatients
by Roche

Age-Related Macular Degeneration

An Observational Study of the Progression of Intermediate Age-Related Macular Degeneration

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	7 Countries	NCT05300724 2022-000046-15 GE43220

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 Multicenter, Prospective, Observational Study of the Progression of Intermediate Age-Related Macular Degeneration

Trial Summary:

This is a multicenter prospective study in participants with intermediate age-related macular degeneration (iAMD). One primary objective of this study is to assess iAMD disease progression, by the timeline and rates of conversion for high-risk iAMD at baseline to more advanced atrophic AMD stages. The other primary objective of this observational study is to assess the feasibility of measuring the rate of photoreceptor loss as a potential clinical endpoint. The study will consist of an observation period of approximately 3 years (~144 weeks) for participants.

Genentech, Inc.	N/A
Sponsor	Phase

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Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#50 Years & # 94 Years	No

Inclusion Criteria:

- For women of childbearing potential, agreement to remain abstinent (refrain from heterosexual intercourse) or use contraception, during the study for at least 28 days after the last fluorescein injection for the fluorescein angiography (FA) administration
- Study eye: High-risk intermediate AMD

Exclusion Criteria:

- Macular disease in either eye with subretinal deposits not typical of AMD
- Pigmentary abnormalities of the retina in either eye not typical of AMD
- Atrophy in either eye due to causes other than AMD
- Study eye: Any concurrent or history of ocular or intraocular condition
- Study eye: Intraocular surgery, including cataract surgery, within 3 months prior to Day 1
- Study eye: Retinal tears or peripheral retinal breaks within 3 months prior to Day 1
- Study eye: Concurrent or history of retinal laser photocoagulation or anti-vascular endothelial growth factor (anti-VEGF) treatment for exudative MNV, diabetic macular edema, retinal vein occlusion, or proliferative diabetic retinopathy
- Study eye: Presence of choroidal nevus with overlying drusen in the circle with a radius 3600 micrometer centered on the fovea
- Study eye: Previous participation in interventional clinical trials for GA or early stages of AMD, except for vitamins and minerals, regardless of the route of administration within the last 6 months, except for sham-arm participants
- Study eye: History of glaucoma surgery, corneal transplant, retinal pigment epithelium tear, retinal tear that involves the macula, retinal detachment
- Either eye: Uncontrolled progressive glaucoma
- Either eye: Moderate or severe non-proliferative diabetic retinopathy or proliferative diabetic retinopathy
- Either eye: History of recurrent infectious or inflammatory ocular disease
- Any concurrent or history of taking medications that can induce retinal toxicity