

Progression of Early Atrophic Lesions

NCT05959005

Status	RECRUITING
Sponsor	University of Utah
Enrollment	125 participants

Key Eligibility Criteria

Inclusion (6)

- Males and females aged 50 years and older of all ethnicities.
- Study eye with at least one early atrophic lesion defined as:
 - incomplete retinal pigment epithelium (RPE) and outer retinal atrophy (iRORA) (region of signal hypertransmission into the choroid, corresponding zone of attenuation or disruption of the RPE, and evidence of overlying photoreceptor degeneration that is, subsidence of the inner nuclear layer (INL) and outer plexiform layer (OPL), presence of a hyporeflective wedge in the Henle fiber layer (HFL), thinning of the outer nuclear layer (ONL), disruption of the external limiting membrane (ELM), or disintegrity of the ellipsoid zone (EZ), or
 - complete RPE and outer retinal atrophy (cRORA) (homogeneous choroidal hypertransmission, absence of the RPE band measuring $\gt 250\mu\text{m}$, evidence of overlying photoreceptor degeneration) and total lesions size $\leq < \frac{1}{2}$ disc area (DA) (corresponding to 1.27mm² area) of all atrophic lesions measured on fundus-autofluorescence (FAF) imaging in the study eye.
- Sufficiently clear ocular media, adequate pupillary dilatation, and adequate fixation to permit quality fundus imaging and unbiased functional testing incl. fundus-controlled perimetry (FCP) testing.

... and 1 more (see full listing online)

Exclusion (11)

- Signs or exudation defined as serous detachment of the sensory retina, intraretinal cystoid fluid, or subretinal/retinal hemorrhage in the study eye.
- cRORA lesion $\gt \frac{1}{2}$ disc area in the study eye at baseline.
- Any history of treatment of exudative macular neovascularization (MNV) in the study eye (e.g. type 1, type 2, mixed, polypoidal choroidal vasculopathy, and retinal angiomatous proliferation); Note: Non-exudative type 1 MNV in the study eye is NOT an exclusion criterion; non-exudative or exudative MNV in the fellow eye is not an exclusion criterion. Fellow-eyes may receive treatment of exudative MNV as part of clinical care.
- Any disease/disorder other than AMD in the study eye at the time of inclusion (e.g. monogenic retinal diseases, diabetic retinopathy, retinal detachment, previous retinal surgeries, myopic degeneration), uncontrolled glaucoma with intraocular pressure (IOP) of $\gt 30$ mmHg (despite current pharmacological or non-pharmacological treatment) and uveitis.
- History of central retinal laser treatment, including photodynamic therapy (PDT) and subthreshold laser treatment for AMD in the study eye.

... and 6 more (see full listing online)

Locations (1 total)

University of Utah, Salt Lake City, Utah, United States

<https://clinicaltrials.gov/study/NCT05959005>

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