

A Phase 2/3 Trial to Assess the Efficacy and Safety of OCU410ST for Stargardt Disease

NCT05956626

Status	RECRUITING
Phase	Phase 2, Phase 3
Sponsor	Ocugen
Enrollment	51 participants

Key Eligibility Criteria

Inclusion (5)

- Males or females aged e5 years at the time of consent.
- Subjects who have confirmed clinical and CLIA certified or equivalent genetic diagnosis of Stargardt disease (including ABCA4 related retinopathies).
- Adult subjects who have BCVA of 75 letters or less in the study eye (20/32 Snellen equivalent) and Pediatric subjects who have a BCVA of 35 letters or better in the study eye (20/200 Snellen equivalent).
- The study eye should have at least one well-demarcated area of atrophy with a minimum diameter of 300 microns, and total lesion size must add to less than or equal to d 18 mm² (approximately 7-disc areas).
- Have detectable outer nuclear layer (ONL) in the macular region

Exclusion (6)

- Participation in ongoing antiretroviral therapy treatment.
- Participation in any experimental treatment or research study within 60 days before screening (any previous eye treatments involving gene therapy, stem cells, implanted retinal chips, injections into the eye, or participation in an Alkeus ALK-001 study within the past 6 months)
- Macular atrophy secondary to any disease other than Stargardt Disease (STGD).
- Presence of genetic mutations that mimic Stargardt Disease like ELOVL4, or PROM1.
- Contraindication to subretinal injection or use of anesthesia (local and/or general).

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

Locations (14 total)

Associated Retina Consultants, Phoenix, Arizona, United States
Retinal Consultants Medical Group, Sacramento, California, United States
Vitreo Retinal Associates, P.A., Gainesville, Florida, United States
... and 11 more locations

<https://clinicaltrials.gov/study/NCT05956626>

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