An Observational Study in Subjects to Follow the Progression of Stargardt Disease Type 1 (STGD1) Caused by Bi-Allelic Autosomal Recessive Mutations in the ABCA4 Gene

NCT06435000

Status	RECRUITING
Sponsor	Splice Bio
Enrollment	75 participants

Key Eligibility Criteria

Inclusion (11)

- Provide written consent
- Are male or female aged 12-65 years old
- Have a diagnosis of STGD1 caused by bi-allelic likely pathogenic or pathogenic variants in the ABCA4 gene confirmed genotypically by an accredited genotyping laboratory
- Have a history of STGD1 progression within the last 2 years, in the opinion of the investigator.
- Eligible eye(s) must have:

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

Exclusion (12)

- Are an immediate family member (e.g., child, sibling) of the Sponsor or study site personnel.
- Have any concurrent ocular disease that would affect study procedures or outcomes (e.g., cataracts; subjects can be enrolled 90 days after successful cataract surgery) in eligible eyes.
- Have two likely pathogenic or pathogenic variants (not STGD1) in autosomal recessive inherited retinal dystrophy (IRD) genes or a single likely pathogenic or pathogenic variant in autosomal dominant or X-linked IRD genes.
- Have had any intraocular surgery or thermal laser within 90 days of study entry or any prior thermal laser in the macular region within the eligible eye(s).
- Have any major surgical procedure within 30 days of the Screening Visit or planned or anticipated major surgery during the study period.

... and 7 more (see full listing online)

Locations (20 total)

Shiley Eye Institute, San Diego, California, United States
UCHealth Sue Anschutz-Rodgers Eye Center, Aurora, Colorado, United States
Vitreo Retinal Associates, Gainesville, Florida, United States
... and 17 more locations

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