Oral Metformin for Treatment of ABCA4 Retinopathy

NCT04545736

Status	RECRUITING
Phase	Phase 1, Phase 2
Sponsor	National Eye Institute (NEI)
Enrollment	56 participants

Key Eligibility Criteria

Inclusion (24)

- Participant must be at least 12 years of age.
- Participant (or legal guardian) must understand and sign the protocol s informed consent document.
- Participant must have at least one definite pathogenic or likely pathogenic mutation in ABCA4 and a typical clinical presentation of Stargardt disease and phenotypic presentation of ABCA4 retinopathy in both eyes.
- Participant must have at least two years of natural history data from at least four data points (a) The separation between any two consecutive data points must be at least six months (b) The most recent data point must be at least 4.5 months and no more than 16 months prior to the baseline visit (c)
- Potential participants with three natural history data points may be enrolled to obtain their fourth natural history data point on protocol.

... and 19 more (see full listing online)

Exclusion (15)

- An individual who meets any of the following criteria will be excluded from participation in this study:
- Participant is actively receiving study IP in another investigational study.
- Participant has a condition that would preclude participation in the study (e.g., unstable medical status including blood pressure and glycemic control) by interfering with the participant s ability to engage in the required protocol evaluation and testing and/or comply with study visits.
- Any female participant of childbearing potential that is pregnant or breast-feeding at the time of enrollment or planning to become pregnant during the study.
- Participant has definitive pathogenic or likely pathogenic mutations in RDS/peripherin (PRPH2), PROM1, and/or ELOVL4.

... and 10 more (see full listing online)

Locations (2 total)

National Institutes of Health Clinical Center, Bethesda, Maryland, United States
University of Michigan, Ann Arbor, Michigan, United States