

Safety and Tolerability of Subretinally Injected OPGx-BEST1 in Patients With Best Vitelliform Macular Dystrophy (BVMD) or Autosomal-Recessive Bestrophinopathy (ARB)

NCT07185256

Status	RECRUITING
Phase	Phase 1, Phase 2
Sponsor	Opus Genetics, Inc
Enrollment	10 participants

Key Eligibility Criteria

Inclusion (11)

- Individuals who meet all the following criteria will be eligible to participate in the study:
- Provide informed consent to study assessments.
- Able and willing to comply with all study assessments for the duration of the study.
- e18years old.
- ETDRS BCVA measured with standard testing distances:
... and 6 more (see full listing online)

Exclusion (21)

- Individuals who meet any of the following criteria will not be eligible to participate in the study.
- Women of childbearing potential (WOCBP) who are pregnant, lactating, and/or unwilling to use effective contraception from Screening through 1 year after IMP administration. See Section 13.3 (Appendix 3) for contraception guidelines.
- Men who are unwilling to use adequate contraception from Screening through 180 days after IMP administration. See Section 13.3 (Appendix 3) for contraception guidelines.
- Have a pre-existing eye condition or complicating systemic disease that could preclude the planned surgery (e.g., individuals who are immunocompromised, on continuous systemic immunosuppressive treatment or anticipate a need to initiate it for non-study reasons, or unable to take the concomitant immuno-suppressive regimen necessary for IMP administration).
- Have a history of disease that may preclude the individual from study participation (e.g., other bestrophinopathy, such as AOFVD or ADVIRC) or that may interfere with or preclude outcome measure testing as described in the protocol.
... and 16 more (see full listing online)

Locations (4 total)

Children's Hospital Los Angeles, Los Angeles, California, United States
Vitreous Retinal Associates, Gainesville, Florida, United States
Cincinnati Eye Institute, Cincinnati, Ohio, United States
... and 1 more locations