A Phase 1/2 Study to Evaluate the Safety and Efficacy of Intravitreal Administration of BS01 in Patients With Geographic Atrophy Secondary to Dry AMD

NCT07158775

Status	RECRUITING
Phase	Phase 1, Phase 2
Sponsor	Bionic Sight LLC
Enrollment	40 participants

Key Eligibility Criteria

Inclusion (11)

- Signed informed consent obtained before screening.
- Men or women between 50 and 85 years of age inclusive at the time of signing the informed consent.
- Geographic atrophy with some macula foveal involvement secondary to dry AMD.
- Total GA area e 5 and d 17.5 mm2 (2 and 7 disk areas respectively), based on Heidelberg Region Finder or equivalent automated software.
- If GA is multifocal, at least one focal lesion should measure e 1.25 mm2 (0.5 disk area) to ensure measurable focal effects for efficacy evaluation.

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

Exclusion (13)

- Previous therapeutic radiation in the region of the SE.
- Previous treatment with any ocular or systemic gene transfer product.
- Any treatment with an investigational agent in the past 60 days for any condition.
- Women who are pregnant or nursing.
- Known hypersensitivity to topical ocular anesthetics or diagnostic drops to be used during the study.

... and 8 more (see full listing online)

Locations (1 total)

NJ Retina, Edison, New Jersey, United States