

Autologous Transplantation of Induced Pluripotent Stem Cell-Derived Retinal Pigment Epithelium for Geographic Atrophy Associated With Age-Related Macular Degeneration

NCT04339764

Status	RECRUITING
Phase	Phase 1, Phase 2
Sponsor	National Eye Institute (NEI)
Enrollment	20 participants

Key Eligibility Criteria

Inclusion (18)

- Participant Eligibility Criteria:
- Participant must be 55 years of age or older.
- Participant must have a diagnosis of dry AMD, defined as presence (or history, as documented in available color fundus photographs) of at least one medium or large druse (greater than or equal to 63 micrometer diameter) in the macula in at least one eye; AND presence of GA in at least one eye.
- Participant must understand and sign the protocol s informed consent document.
- Any participant of childbearing potential must have a negative pregnancy test at screening and must be willing to undergo pregnancy testing prior to RPE transplantation.

... and 13 more (see full listing online)

Exclusion (15)

- Participant is actively receiving another study medication / investigational product (IP).
- Participant has any condition that significantly increases risk of systemic corticosteroids or systemic steroid-sparing immuno-modulatory agents, such as uncontrolled diabetes mellitus, chronic hepatitis or liver failure, chronic renal failure, or present infection with HIV, syphilis, tuberculosis, hepatitis B, or hepatitis C (past infection now resolved, where applicable, is not exclusionary; but persistent infection, even if latent, is exclusionary).
- Participant has diagnosis of a malignancy expected to affect two-year survival.
- Participant is pregnant, breast-feeding, or planning to become pregnant through the first 12 months of the study.
- Participant has a family history of a retinal degeneration other than AMD suspected to play a role in the ocular phenotype of the participant in the judgment of the investigator, based on disease features and mode of inheritance, such as in a case of autosomal dominant retinal degeneration in a parent or child.

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

Locations (2 total)

Johns Hopkins University, Baltimore, Maryland, United States
National Institutes of Health Clinical Center, Bethesda, Maryland, United States

<https://clinicaltrials.gov/study/NCT04339764>

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