

Pseudophakic

Prospective, Multicenter Clinical Trial of the Implantable Miniature Telescope in Pseudophakic Eyes with Central Vision Impairment Associated with End-Stage Macular Degeneration.

Inclusion

1. Have retinal findings of geographic atrophy or disciform scar with foveal involvement as determined by FA
2. Be age 65 or older
3. Have BCDCA between 20/160 to 20/800 on ETDRS chart
4. Be pseudophakic in the eye selected for telescope implantation
5. Agree to undergo pre-surgery training with a low vision specialist
6. Achieve at least a 5-letter improvement on the ETDRS chart with an external telescope
7. Agree to participate in postoperative vision training with a low vision specialist
8. Subjects must be able to provide a sign voluntary informed consent
9. Subjects must not meet any of the exclusion criteria below

Exclusion

1. Have Stargardt's macular dystrophy
2. Have cognitive impairment that would interfere with the ability to understand instructions, follow directions, or prevent proper visual training/rehabilitation with the device
3. Any ophthalmic pathology that compromises fellow-eye peripheral vision
4. Have a history of steroid-responsive rise in IOP, uncontrolled glaucoma, or preoperative IOP >22mm Hg while on maximum medication
5. Subjects with known sensitivity to planned study concomitant medications
6. Subjects with an ocular condition that predisposes the subject to eye rubbing
7. Subjects participating in any other ophthalmic drug or device clinical trial during the time of this clinical investigation
8. Operative eye with:
 - a. Evidence of active CNV or treatment of CNV within 6 months
 - b. IOLs of the following types: PMMA, Crystalens, Tetraflex, Synchrony
 - c. Anterior chamber depth <3.0 mm; measurement of the ACD should be taken from the posterior surface of the cornea (endothelium) to the anterior surface of the IOL.
 - d. Axial length <21 mm or >27 mm
 - e. Endothelial cell density (ECD) lower than 2300 cells/mm² for subjects between the ages of 70-74, and lower than 1800 cells/mm² for subjects 75 years old or greater
 - f. Corneal stromal or endothelial dystrophies, including guttata
 - g. History of intraocular or corneal surgery (including DSEK), except cataract removal and IOL placement
 - h. History of complicated cataract surgery
 - i. Compromised capsular bag (previous YAG posterior capsulotomy, evidence of tearing)
 - j. History of radial keratotomy

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- k. Inflammatory ocular disease
- l. Pseudoexfoliation or zonular weakness
- m. Diabetic retinopathy
- n. Untreated retinal tears
- o. Retinal vascular disease
- p. Optic nerve disease
- q. A history of retinal detachment
- r. Intraocular tumor
- s. Retinitis pigmentosa
- t. Prior or expected ophthalmic related surgery within 30 days preceding telescope implantation
- u. Any medical or ophthalmic condition that in the opinion of the investigator renders the subject unsuitable for participation in the study