Efficacy and Safety of ZVS101e in Patients With Bietti 's Crystalline Dystrophy

NCT06743646

Status	RECRUITING
Phase	Phase 3
Sponsor	Chigenovo Co., Ltd
Enrollment	62 participants

Key Eligibility Criteria

Inclusion (4)

- Fully understand the purpose and requirements of this trial, voluntarily participate in the clinical trial and sign the informed consent form, and be able to complete all trial procedures as required by the protocol;
- Clinical diagnosis of Bietti's crystalline dystrophy (BCD), agee18 years ;
- Genetic testing confirmed biallelic CYP4V2 mutations without other ophthalmic genetic diseases;
- Best-corrected visual acuity of 5-60 ETDRS letters.

Exclusion (5)

- The study eye has or has had macular lesions such as macular hole or macular neovascularization; glaucoma, diabetic retinopathy, or any other ocular disease that may preclude surgery or interfere with interpretation of the study endpoints
- The study eye had received the following intraocular surgical treatments: retinal reattachment, vitrectomy;
- The study eye had received any intraocular surgery, such as phacoemulsification 3 months prior to enrollment;
- Previously treatment of either eye with gene therapy or stem cell therapy for BCD and other ocular diseases, including but not limited to viral vector gene therapy, RNA therapy;
- Pregnant or lactating women;

Locations (8 total)

Peking University Third Hospital, Beijing, Beijing Municipality, China
Zhongshan Ophthalmic Center, Sun Yat-sen University, Guangzhou, Guangdong, China
The First Affiliated Hospital of Harbin Medical University, Haerbin, Heilongjiang, China
... and 5 more locations