

Safety and Efficacy Study of PUMCH-E101 Injection in Subjects with RDH12 Retinopathy

NCT06749639

Status	RECRUITING
Phase	Early Phase 1
Sponsor	Peking Union Medical College Hospital
Enrollment	10 participants

Key Eligibility Criteria

Inclusion (5)

- Subjects voluntarily participate and sign the informed consent form;
- Age between 8-45 years old, gender is not limited;
- Clinical diagnosis of IRD caused by RDH12 mutations;
- The Best Corrected Visual Acuity (BCVA) detected by the Early Treatment Diabetic Retinopathy Study (ETDRS) eye chart in the study eye is less than or equal to 63 letters, which is equivalent to 20/63 of the Snellen Eye Chart;
- At screening, the blood pregnancy test result of females of childbearing potential (e.g., females who have not undergone surgical sterilization or less than 1 year after menopause) is negative. Male and female subjects of childbearing potential agree to use effective contraception throughout the study and for at least 12 months after dosing.

Exclusion (23)

- Opacity of refractive media or inability to dilate pupils in the study eye that significantly interferes with visual acuity detection, anterior segment or fundus assessment;
- Presence of diabetic retinopathy, retinal vein occlusion, pathological myopia, retinal detachment, or other conditions in the study eye that are assessed by the investigator as affecting the safety of the subject or the validity of the study;
- Any intraocular surgery in the study eye within 3 months prior to screening;
- Active intraocular or periocular infection (such as blepharitis, conjunctivitis, keratitis, scleritis, etc.) in the study eye;
- History of uveitis in either eye

... and 18 more (see full listing online)

Locations (1 total)

Peking Union Medical College Hospital, Beijing, Beijing Municipality, China