

The Effectiveness and Safety of Two Low-concentration Atropine Sulfate Eye Drops (0.01%/0.02%) for Delaying the Pediatric Myopia Progression

NCT06708156

Status	RECRUITING
Phase	Phase 3
Sponsor	Oupushifang Pharmaceutical Technology Co., Ltd.
Enrollment	606 participants

Key Eligibility Criteria

Inclusion (6)

- The legal guardian of the subject voluntarily signed the written informed consent, and the subject over 8 years is required to sign the written informed consent voluntarily.
 - Patients with myopia aged 6 to 12 years, including cut-offs.
 - The equivalent spherical refraction ranges from -1.00 D to -4.00 D (automatic optometry under a cycloplegia condition) in both myopia eyes at inclusion screening.
 - The astigmatism of both eyes was ≤ 1.50 D under a cycloplegia condition at inclusion screening.
 - The antimetropia (measured by equivalent spherical refraction) is ≤ 2.00 D at inclusion screening.
- ... and 1 more (see full listing online)

Exclusion (12)

- Allergic to this product or its excipients.
 - Suffering from eye diseases that may affect vision (e.g. lens diseases such as cataracts, glaucoma, fundus macular disease, keratopathy, uveitis, retinal detachment, severe vitreous opacity, etc., manifest strabismus, nystagmus, ocular acute inflammatory disease), history of recurrent chronic ocular inflammation, or any other ocular pathology (e.g., angular stenosis, shallow anterior chamber).
 - Intraocular pressure of either eye is > 21 mmHg or < 10 mmHg at screening.
 - Use of low-concentration (0.05% and below) atropine sulfate eye drops (including various in-hospital preparations, except for test drugs) and orthokeratology lenses (OK lenses) within 6 months before the screening.
 - Use of other myopia control methods such as instruments (multifocal glasses, progressive multifocal glasses, etc.), medications (the use of cycloplegic agents for examinations such as optometry is allowed), and others (including traditional Chinese medicine, auricular acupuncture, massage, accommodative flippers, red light therapy instrument, etc.) within 3 months before screening.
- ... and 7 more (see full listing online)

Locations (25 total)

Hefei Maternal and Child Health Hospital, Hefei, Anhui, China
The Second Hospital of Anhui Medical University, Hefei, Anhui, China
Xuancheng People's Hospital, Xuancheng, Anhui, China
... and 22 more locations

<https://clinicaltrials.gov/study/NCT06708156>

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