PROTECT Study: A Prospective Study on Optimizing the Atropine Concentration Staircase Protocol for Myopia Prevention in Children

informed consent

Test drug:	**Atropine Sulfate Eye Drops (0.01%,0.02%,0.04%)**
Group leader unit:	**Ophthalmology Hospital of Tianjin Medical University**
Principal Investigator:	**Wei Ruihua**
Organization:	**Ophthalmology Hospital of Tianjin Medical University**
Principal Investigator of the Unit:	**Wei Ruihua**
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Dear Parents:

We invite your child to participate in the clinical study "PROTECT Study: A Prospective Study on Optimizing the Atropine Concentration Staging Protocol for Myopia Prevention in Children," approved by the Ophthalmology Hospital of Tianjin Medical University. This study is led by Professor Wei Ruihua from the Optometry Center and will be conducted jointly by 16 hospitals, including the Ophthalmology Hospital of Tianjin Medical University, the Affiliated Hospital of Guizhou Medical University, and the First People's Hospital of Foshan. It is estimated that 233 participants will voluntarily enroll, with each center allocating the number of cases based on actual conditions. Our center plans to enroll 20 participants. This study has been reviewed and approved by the Ethics Committee of the Ophthalmology Hospital of Tianjin Medical University.

Why was this study conducted?

Myopia has become a major public health issue threatening children's eye health, with China ranking first in the world in the prevalence of childhood myopia. High myopia is prone to cause irreversible complications such as retinal detachment and macular degeneration, significantly increasing the risk of blindness. Delaying the onset of myopia by one year can ultimately reduce the final myopia level by at least 0.75D, making effective prevention of myopia development critically important.

0.01% atropine sulfate eye drops have been widely used in clinical practice for myopia prevention and control, with their efficacy in delaying myopia progression and safety having been preliminarily validated. However, the preventive effects and safety of other concentrations (0.02% and 0.04%) require further validation. This study adopted a prospective, multicenter clinical trial design to investigate the efficacy of switching to higher-concentration (0.02% and 0.04%) atropine eye drops in children with insufficient hyperopia reserve who exhibit poor response to 0.01% atropine eye drops, aiming to delay myopia progression. Additionally, the study explored the threshold for myopia progression in children using 0.01% atropine eye drops when switching to higher-concentration (0.02% and 0.04%) atropine eye drops, providing a scientific basis for rational clinical medication to prevent myopia and ultimately reduce the burden of myopia in children.

Who can participate in the study?

1. Written informed consent was obtained from the child and legal guardian.
2. Children aged 6-9 years (inclusive).
3. After bilateral ciliary muscle paralysis, the equivalent spherical diopter of computerized refraction is 0D<SE. The upper limit standards of SE for different age groups are: 6 years old: +1.13D,7 years old: +1.00D,8 years old: +0.88D,9 years old: +0.63D.
4. After bilateral ciliary muscle paralysis, the computerized refraction showed astigmatism ≤ 1.00D and anisometropia ≤1.5D.
5. No other organic lesions affecting visual acuity in both eyes, with uncorrected visual acuity ≥ 0.8 and

intraocular pressure ≤21 mmHg.

Who should not participate in the study

1. Subjects who may have ocular diseases affecting vision or refractive errors (such as lens damage diseases like cataracts, glaucoma, macular degeneration, corneal lesions, uveitis, retinal detachment, severe vitreous opacity, etc.).
2. Systemic diseases: immune system disorders, central nervous system diseases, Down syndrome, asthma, severe cardiopulmonary dysfunction, and a history of severe hepatic or renal dysfunction.
3. Bilateral or unilateral ocular involvement with dominant strabismus or any other pathological ocular changes or acute inflammatory eye diseases.
4. Treatment methods for myopia control include: pharmacological therapy (e.g., atropine or pilocarpine); orthokeratology lenses, multifocal soft lenses, multifocal hard lenses, or functional eyeglass frames; and red light therapy.
5. Use of drugs affecting efficacy evaluation (e.g., anticholinergic agents: atropine, piperazine; cholinergic agents: pilocarpine) systemically or topically within the preceding 3 months.
6. Patients with hypersensitivity to atropine, cyclopentolide, or other drugs used in this study.
7. Participants who had participated in other drug clinical trials within the first 3 months prior to screening.
8. Other circumstances deemed unsuitable by the investigator.
9. patients with chronic mental disorders or psychiatric abnormalities
10. those with a modulation amplitude below 8D

How was this study conducted?

This clinical study will be conducted simultaneously in 16 hospitals in China, with 233 participants planned to join the study. The study adopts a single prospective, multicenter design, divided into a screening period (D-14 to D0) and a trial period (using eye drops for 12 months). During the screening period, doctors will conduct a series of examinations on your child to determine if they meet the enrollment criteria. After enrollment, based on the grouping method:

1. Phase 1: 0-24 weeks (0-6 months). 0.01% atropine eye drops, once daily, instilled into both eyes.
2. Phase 2: 24-48 weeks (6-12 months). Based on the progression rate of myopia from 0-24 weeks (6 months), the atropine concentration is incrementally increased; administered once daily, instilled into both eyes.

    - Group A: ($\Delta SE \leq 0.25D$), continued administration of 0.01% atropine.
    - Group B: ($0.25D < \Delta SE \leq 0.375D$), switched to 0.02% atropine.
    - Group C: ($\Delta SE > 0.375D$), switched to 0.04% atropine

You are required to bring your child for follow-up visits at the 3rd month (±2 weeks), 6th month (-2 weeks),

9th month (±2 weeks), and 12th month (-2 weeks) after medication initiation. If myopia develops during the follow-up (ciliary muscle paralysis refraction SE ≤ -0.5D and uncorrected visual acuity <0.8), single-vision glasses should be prescribed, and the follow-up should be completed.

After 6 months of self-administered medication, the investigator assessed the progression rate of myopia and whether to incrementally increase the atropine concentration, followed by continued research medication administration for 6 months of observational follow-up.

[What are the examination items included]

The examination and evaluation items include: computerized refraction and corneal curvature in non-ciliary muscle paralysis, visual acuity (unaided visual acuity, best-corrected distance and near visual acuity in non-ciliary muscle paralysis), intraocular pressure, ocular biological parameter measurements (axial length, anterior chamber depth, pupillary diameter, corneal curvature), accommodation range, slit lamp examination, ocular position and ocular motility, ciliary muscle paralysis and computerized refraction in ciliary muscle paralysis, fundus photography, choroidal thickness and blood supply, optical correction fitting, inquiry of transportation costs to the hospital, risk factor questionnaire, medication adherence assessment, treatment satisfaction questionnaire, visual quality questionnaire, and post-medication ocular tolerance survey.

[Benefits of Participating in the Study]

Your child may receive direct medical benefits, such as: the progression of myopia in your child may be delayed, reducing the risk of future myopia and severe ocular complications associated with high myopia. The relevant examinations for the study are free, and the second-phase follow-up may include a trial medication. If myopia occurs during the follow-up and vision deterioration requires glasses, free monocular glasses fitting will be provided to reduce your family's medical expenses. However, this study does not provide transportation subsidies for follow-up visits. Your child's participation will provide valuable data for the application of 0.01%,0.02%, and 0.04% atropine sulfate eye drops in the prevention of myopia in children and adolescents in China, which will help guide future clinical rational medication and benefit more children.

During the follow-up period, your child will receive one-on-one priority medical services provided by the investigator. Based on the examination results of your child, the physician will develop a personalized treatment plan for the child.

[Risks of Participating in the Study]

It is known that atopic eye drops containing 0.01%,0.02%, or 0.04% atropine may cause varying degrees of photophobia, glare, blurred near vision, and local allergic reactions during the initial use period. During the initial phase of medication, your child may experience symptoms such as photophobia, glare, or blurred near vision to varying degrees. To address potential adverse reactions, the research team will implement corresponding measures: For intolerable photophobia or glare, wearing tinted glasses can be used to alleviate symptoms; for blurred near vision caused by insufficient accommodation function, accommodation training can be employed to improve the condition; if other adverse reactions such as allergic conjunctivitis occur, the physician will provide symptomatic treatment based on the specific circumstances. Additionally,

although the probability is extremely low, other unforeseen adverse events not within the known range of adverse reactions may still occur.

If your child suffers any harm related to this clinical study due to participation in the research, your child may be eligible for free treatment and/or corresponding compensation. The treatment costs will be covered by the insurance company and the sponsor in accordance with the relevant economic compensation or indemnification requirements under the laws and regulations of the People's Republic of China.

[Alternative Treatment Options for Non-Participants in This Study]

Current preventive measures for myopia primarily include increasing outdoor activities, reducing near-vision tasks, and wearing certain functional eyeglasses. If you and your child choose not to participate in this clinical trial, your child's physician will discuss appropriate preventive strategies based on your refractive status and ocular health condition.

[Should I participate in the study?]

Participation in this study is entirely voluntary. You and your child may opt out of the study or withdraw at any time during the research process, which will not affect the treatment of your child by the physician. If you decide to withdraw from the study, please promptly contact the study physician of your child. To safeguard your child's health, the physician may recommend a relevant ophthalmic examination prior to withdrawal to assess the current ocular condition of your child.

Is personal information confidential?

All personal medical records of your child during the study (including test results, medical history, medication records, adverse event logs, etc.) will be strictly confidential and used solely for the analysis and reporting of this study, not for any other purposes. These medical records will be stored in dedicated filing cabinets or encrypted electronic systems at each participating institution. Only authorized researchers, ethics committees of the participating institutions, and relevant regulatory agencies such as drug regulatory authorities will have access to these records when performing their duties or in response to regulatory requirements.

Any public reports, academic papers, or conference communications related to the results of this study will not disclose the personal identity of your child. We will make every effort to protect the personal privacy and medical information security of your child within the scope permitted by law.

For inquiries regarding personal rights and interests, please contact the Ethics Committee of this hospital at the following telephone number:_____

Subject Statement: I have read the above introduction regarding this study and fully understand the potential risks and benefits associated with participation in this study. I consent to my child's voluntary participation in this study. I will receive a copy of this informed consent form signed with my name and date.

I agree □ or decline □ to the use of my child's medical records and examination specimens for any research other than this study.

Signature of legal representative/witness: _

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Signature of legal representative/witness: _

Contact information for legal representative/witness:

Researcher's Statement: I hereby confirm that the detailed information regarding this study, particularly the potential risks and benefits associated with participation, has been explained to the patient's parents. All relevant questions raised by the parents have been addressed, and they have voluntarily consented to their child's participation in this study. This informed consent form is prepared in duplicate, with one signed copy retained by the researcher and the other by the parent of the subject.

Research Physician Signature: Date: _ Research Physician Signature: Date: _

Contact information for the attending physician:___________________________