Efficacy and Safety of 1% Atropine 5+3 Regimen in Children and Adolescents Controlling Myopia

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Research Background

Studies have shown that atropine eye drops are effective in controlling myopia in children and adolescents. Among them, low-concentration atropine has few side effects and is the primary recommendation, but many clinical practices and studies suggest that its effect in controlling myopia is limited. 1% atropine ophthalmic drug has obvious curative effect advantages in controlling myopia, but its side effects such as photophobia and blurred vision limit its popularization and use. In the early stage, our research group used 1% atropine "5+3" myopia control (eye instillation for 5 consecutive nights in the first week of each month, one night per week in the 2nd, 3rd, and 4th weeks; after 3 months of monocular application, change to the contralateral eye), data from retrospective clinical studies have shown that it can significantly reduce side effects and improve compliance, but there is currently a lack of evidence from prospective clinical studies. Therefore, this study intends to use a randomized controlled trial, with 1% atropine used in both eyes once a week as the control group, to evaluate the effect of the "5+3" regimen in controlling myopia (spherical equivalent and axial length), safety (accommodation amplitude, amount of phoria, binocular vision function, etc.), and the compliance and side effects (photophobia, blurred vision, etc.).

Research purposes

To observe the efficacy and safety of 1% atropine ophthalmic "5+3" regimen in controlling myopia in children and adolescents

Research content

This study was designed as a prospective, randomized controlled clinical study

Grouping

96 people in the 1% atropine 5+3 group

96 people in the 1% atropine weekly group

Children mainly from the optometry clinic of Shanghai Eye Disease Control Center

Inclusion criteria

1. Age 6 to 12 years old;

2. Both eyes are in line with the diagnosis of myopic refractive error and 0.25D < myopia spherical lens <4.00D after mydriasis, astigmatism <2.00D, binocular anisometropia <3.00D,

and the best corrected distance vision is at least 0.8, myopia The force is at least 0.8;

3. Visual function: Timus≤100 seconds, exophoria <5△, accommodation amplitude (AMP) ≥ age-related minimum accommodation amplitude value (minimum accommodation amplitude=15-0.25×age);

4. No contraindications for atropine treatment such as acute eye inflammation, dry eye, keratoconus, diabetes, etc.;

5. The written informed consent of the guardian and the child himself.

Exclusion criteria

1. History of photosensitivity, glaucoma, blue eye syndrome, ocular hypertension, fundus macular lesions or damage;

2. Corneal curvature examination, the average K value of the anterior surface of the cornea is ≥45;

3. Patients with ocular trauma, oblique or surgical eyes, atopic keratoconjunctivitis and other chronic eye diseases;

4. Those with previous ophthalmia, severe angular, conjunctival infection and other eye diseases;

5. Patients with neurological diseases and allergic or contraindications to atropine or other therapeutic drugs;

6. Received other treatments to control the development of myopia in the past, such as the use of anticholinergic drugs such as atropine within 3 months, or participated in other relevant researchers such as functional frame mirrors and multifocal flexible mirrors;

7. Other circumstances judged by the investigator to be unsuitable to participate in the research.

Interventions

1. 1% atropine 5+3 group

   1% atropine eye drops used for 5 consecutive nights in the first week of each month, one night per week in the 2nd, 3rd, and 4th weeks; after 3 months of monocular application, change to the contralateral eye

   Total treatment time 1 year

2. 1% atropine weekly group

   1% atropine eye drops once a week in both eyes

   Total treatment time 1 year

Outcome

Main outcomes

Spherical equivalent and axial length before atropine treatment, and 1, 3, 6, 9, 12 months after treatment

Secondary outcomes

safety (accommodation amplitude, amount of phoria, binocular vision function), and the compliance and side effects (photophobia, blurred vision, etc.) before atropine treatment, and 1, 3, 6, 9, 12 months after treatment

Other outcomes

Changes in uncorrected visual acuity, corrected visual acuity, intraocular pressure, pupil diameter, corneal thickness, anterior chamber depth, lens thickness, choroid/retina thickness, and ciliary muscle parameters

Security indicators

1. Observe changes in intraocular pressure, headache, nausea and vomiting, etc.

2. Questionnaire survey: self-perceived photophobia, near blurred vision and other side effects levels

3. Incidence of allergic reactions

Research methods

Sample size

Select the ciliary muscle apex thickness difference after cycloplegia for sample size calculation

α (inspection level) = 0.05

β (test power) = 0.90

Lost to follow-up rate/dropout rate is 20%

The ratio of the two groups of samples is 1:1

The final calculated sample size is 96 (1% atropine 5+3 group) + 95 (1% atropine weekly group) = 192 (total sample size)

grouping

Generate random numbers through a random number table, divide the random numbers by the number of groups, and group them according to the remainder

Technical Risk

After atropine treatment, near vision blurring may occur, and there may be temporary eye burning sensation, stinging pain, and photophobia; for people with near vision blurry, the phenomenon affecting reading needs to be explained patiently, and the subjects should be informed to keep correct reading distance.

1% atropine may cause dry mouth, dry skin and mucous membranes, nausea, facial flushing, palpitations and other symptoms after systemic absorption of atropine. Stop the drug immediately.

A small number of patients have allergic reactions such as itching, redness, and conjunctival hyperemia of the eyelids, and the drug should be discontinued immediately.

In case of increased intraocular pressure, headache, eye pain and vomiting (manifestations of acute angle-closure glaucoma). The solution is to perform initial slit-lamp screening in all subjects before dilation, and patients with very narrow angles will not be dilated. If the subject has symptoms such as increased intraocular pressure, headache, eye pain, etc., timely drug treatment.

Expected results

Prove the efficacy and safety of 1% atropine ophthalmology "5+3" program in the control of myopia in children and adolescents.