Information sheet

Title of project:

Treatment effect of topical application of low-concentration (0.01%) atropine on the human eye with fast and slow myopia progression rate as classified by electro-retinal responses

Project Team:

Dr. Henry Chan (Associate Professor)

School of Optometry, The Hong Kong Polytechnic University (Tel: 2766 7937)

Dr. Alex Ng (Clinical Assistant Professor)

Department of Ophthalmology, The University of Hong Kong (Tel: 2255 5632)

Dr. Lydia Yu (Clinical Optometrist)

School of Optometry, The Hong Kong Polytechnic University (Tel: 3400 2911)

Why is the study being performed?

Short-sightedness (myopia) has been an epidemic worldwide. In Hong Kong, the prevalence of myopia is approximately 80% at the end of childhood, and the rate of myopia progression among children varies. Use of 0.01% atropine is a newly recommended drug treatment for myopia control. Recent studies reported that it is effective to slow down myopia progression. From our recent study, we can use a special measurement to predict the risk of fast myopia progression for each child according to the electrical signal from the retina. In this study, we will study the effect of 0.01% atropine on the children who have been identified with the risk of fast or slow myopia progression. This project helps us better understand the effectiveness of this drug treatment in myopia control for the children with different predisposed risks. It also helps us to develop an optimal protocol to maximize the effect of myopia control treatment. We aim to include 80 subjects in this study with a 1:1 group allocation ratio.

Inclusion criteria:

The subject must:

1. be aged between 7 and 10 years
2. have no reported ocular disorder and no family history of ocular disease
3. be able to participate in this study for 18 months
4. not have any current or history of epilepsy
5. not have any current or history of asthma
6. have refractive error between -0.50D and -4.00D and less than 1.50D of astigmatism with best corrected visual acuity of LogMAR 0.0 or better

7. have no detected ocular diseases or disorders after eye examination, except myopia

What do volunteers have to do for this study?

If you agree to have your child volunteered to participate in this study, you will be asked to:

1. sign an informed consent form for your child that states you on behalf of your child understand the study information. In addition, your child will also be asked to sign an accent form to state that he/she agrees to participate in this study.
2. provide your child's personal information including name, date of birth and contact number.

If, and only if, your child meets the subject inclusion criteria (item 1-5) of this study, your child will be asked to:

1. attend a comprehensive eye examination including cycloplegic refraction and ocular health assessment. Optometrist will administrate 2 drops of 1% Cyclopentolate to dilate the pupil and paralyze the ciliary muscle for the relaxation of accommodation, in order to obtain more accurate refractive status and exam the eye. It takes about 45 minutes for the drug to exert its effect and approximately 18 hours to recover. Then different ocular parameters including length of eyeball and eye pressure will be measured and fundus photos of the eyes will be taken. This eye examination lasts for about 2 hours;
2. if your child meets the subject inclusion criterion (item 6-7) of this study, your child will be asked to attend an electrophysiological assessment (multifocal electroretinogram (mfERG)) at the Polytechnic University. It will take about 30 minutes to complete the electrophysiological assessment and both eyes will be recorded simultaneously;
3. another visit will be arranged to have the consultation by an ophthalmologist at the eye clinic of Grantham Hospital. In this visit, your child will be randomly allocated into treatment or placebo groups. You will receive the packs of eye drops vials (treatment drug or placebo) for daily instillation over 3-month period. You and your child should fill the logbook given for the record of compliance;
4. A follow-up consultation will be conducted by the ophthalmologist in every 3-month to review the condition and to deliver another 3-month supply of eye drops;
5. A follow-up eye examination will be conducted by the optometrist in every 6-month to review refraction (including cycloplegic refraction), different ocular parameters, eye health and electrophysiological assessment. Each visit lasts for about 2.5 hours;
6. your child has to attend total 7 consultations by ophthalmologist and total 4 eye

examinations by optometrist over 18 months.

Schedule of visits

1st visit	Comprehensive eye check and electrophysiological measurement
2nd visit	Consultation by Ophthalmologist and receiving 1st 3-month eye drops
3rd visit	Consultation by Ophthalmologist and receiving 2nd 3-month eye drops
4th visit	Follow up eye check and electrophysiological measurement
5th visit	Consultation by Ophthalmologist and receiving 3rd 6-month eye drops
6th visit	Follow up eye check and electrophysiological measurement
7th visit	Consultation by Ophthalmologist and receiving 4th 6-month eye drops
8th visit	Last follow up eye check and electrophysiological measurement
9th visit	Last consultation by Ophthalmologist

* Ophthalmologist assessment: Eye clinic, Grantham Hospital
Electrophysiological measurement: Optometry clinic, Polytechnic University

Procedure for electrophysiological examination

1. Sensors placement

A thread-like sensor will be placed on the lower lid of the eye, and the cup-like sensors will be placed 10 mm next to the eyes, the central forehead, posterior skull and earlobe. The refractive error of the tested eye will be fully corrected for the viewing distance.

2. Your child sits in front of the screen.

3. Your child will be asked to fixate on a red cross at the center of the monitor during the recording process without blinking, and will be given a rest between test intervals.

Is there any benefit or risk for the volunteer who participates in the study?

Risks:

The risks are minimal. Your child will be instilled with 2 drops of 1.0% Cyclopentolate, which are common diagnostic eye drops in general ophthalmic practice for accurate assessment of refractive status and ocular health for children. These eye drops may have mild stinging sensation for a few seconds but do no harm your child's eyes. Some people may develop transient adverse effects such as blur vision, red eye, glare sensation, weakening the near vision ability and swollen eye after the instillation of the eye drops. The possible risks include narrowing the anterior angle resulting in acute angle-closure glaucoma but the chance is very low. Our optometrist will assess the suitability of the eye to use the diagnostic eye drops before instillation in order to keep the risk minimal. Only the suitable subjects will be

allowed to join the study. The effect of the diagnostic agent will last for about 18 hours in which your child may experience blur at near and photophobia during this period. Your child is recommended to avoid near works until the effect of eye drop disappears. Wearing sunglasses is suggested during this period.

Traditionally, high concentration of atropine (i.e. 1%) is also a common diagnostic eye drop in general ophthalmic practice for accurate assessment of refractive status for children. Its adverse effects are very similar to Cyclopentolate. After instillation of atropine, your child may have mild stinging sensation for a few seconds but do no harm your child's eyes. Some people may develop transient adverse effects such as blur vision, red eye, glare sensation, weakening the near vision ability and swollen eye after the instillation of the eye drops. The effect of the diagnostic agent will last for about 18 hours in which your child may experience blur at near and photophobia during this period.

In this study, a very low concentration of atropine (0.01%) will be used as myopia control treatment and be given to the subjects in the treatment group. Since the concentration is much lower than the high concentration atropine used for diagnostic purpose, the above mentioned adverse effects will be less. According to previous reports, the long term use of 0.01% atropine for myopia control may have the following additional adverse effects. For example, allergic conjunctivitis (4.1%), allergy-related dermatitis of the eyelids (1.3%), ocular irritation (1.2%), blur vision (1.2%), and glare intolerance (0.6%). In addition, there were some reported very rare cases requiring hospitalization, including acute gastric pain (0.3%), appendicitis (0.3%), respiratory infection (0.3%), Ewing's sarcoma (0.3%), tachycardia (0.3%), dengue fever (0.3%) and gastroenteritis (0.3%). However, none of these events had direct association with the use of atropine.

You will be educated to differentiate minor discomfort from complications, eg. allergic conjunctivitis, acute glaucoma attack, etc., that require immediate medical treatment. You may contact Dr. Alex Ng (Ophthalmologist) during office hours or Dr. Lydia Yu (Optometrist) both office and non-office hours if you have any problems of your child after instilling the eye drops.

Benefit:

Your child who fit for the inclusion criteria can receive a series of eye examinations over 18 months performed by a registered optometrist in which the required fee will be covered by this project. Also, children may have chance to receive this drug treatment for myopia control.

Can a volunteer withdraw from the study?

Yes, your child can withdraw from the study at any time without any penalty or affecting your child's future eye care.

Alternatives

Your participation is voluntary. Your refusal to participate will not change any of your medical care, and you will not lose any benefits you have now. You may stop participation at any time without any changes or loss of your medical care. Your investigator can withdraw you from the study without your consent if he or she believes it is necessary for your safety or if you do not follow the study requirements.

Can I get more information on the study?

Yes, you can contact Dr. Henry Chan (Tel: 2766 7937) for any questions you have. He will try to answer all questions you have.

Confidentiality

Any information that is obtained in this study concerning your child will be confidential. Publication or other public distribution of the experimental results will not mention your child by name. Research records will be stored securely and only members of this project will have access to the records. Raw data will be destroyed 7 years upon the completion of this project.

Thank you for participation of your child.

This study has been approved by the Departmental Research Committee (DRC) of the School of Optometry of The Hong Kong Polytechnic University. If you have any complaints about the conduct of this research study, please do not hesitate to contact the Chairman of DRC (School of Optometry) of The Hong Kong Polytechnic University, in person or in writing.

This study has also been reviewed and approved by the Institutional Review Board of the University of Hong Kong / Hospital Authority Hong Kong West Cluster. For enquiry on the ethical rights of a research subject, please contact the Institutional Review Board (IRB) office at 2255 4086.