Information sheet

Title of project:
Pharmacological (0.05% Atropine) and non-pharmacological (Defocused Incorporated Multiple Segments Lens) treatment effects on the children with different predicted myopia progression rate measured by modified multifocal electroretinogram

Project Team:

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You are invited to participate in the above project conducted by Dr Bonnie Choy who is a staff member of the Department of Ophthalmology in The University of Hong Kong and Prof Henry Chan who is a staff member of the School of Optometry in The Hong Kong Polytechnic University. The project has been approved by the PolyU Institutional Review Board (IRB) (Reference Number: HSEARS20220110002) and the HKU/Hospital Authority Hong Kong West Cluster (HA HKW) IRB (Reference Number: XXXXXXXXXXX)

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 recommended drug treatment for myopia control. Recent studies reported that it is not very effective to slow down myopia progression. Some studies suggested to use the higher dosage of atropine (for example 0.05%) which provides better myopia control.
Apart from atropine, another recent successful myopic control strategy is a novel spectacle lens (Defocused Incorporated Multiple Segments – DIMS) which has demonstrated good myopia

control effect in schoolchildren.
From our previous study, we can use a special measurement to predict the risk of fast myopia progression for each child according to the retinal response. In this study, we will study the effect of 0.05% atropine and the effect of DIMS lens 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 both treatments in myopia control for the children with different risks. It also helps us to develop an optimal method to maximize the effect of different myopia control treatments. 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 9 years
2. have no reported eye disorder and no family history of eye disease
3. be able to participate in this study for 24 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 eye 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 full eye examination including refraction (with pupil dilation) and eye health assessment (e.g., corneal shape and eyeball size measurements, retinal scanning, etc.). Optometrist will administrate 2 drops of 1% Cyclopentolate to dilate the pupil and to relax the accommodation, for obtaining refractive status and examining the eye. It takes about 45 minutes for the drug to exert its effect and approximately 18-24 hours to recover. Then different eye parameters including length of eyeball and eye pressure will be measured and 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 a special assessment for retinal function (multifocal electroretinogram (mfERG))

at the Hong Kong Polytechnic University. It will take about 30 minutes to complete the assessment and both eyes will be recorded simultaneously;

3. another visit will be arranged 6 months later to repeat the full eye examination to review the refractive and eye changes and then your child will allocate into either atropine-treatment or DIMS-treatment groups;

4. for those allocated in the atropine-treatment group, you will be arranged to have the consultation by an ophthalmologist at the eye clinic of Grantham Hospital. In this visit, your child will receive the packs of eye drops vials for daily instillation. You and your child should fill the e-logbook given for the record of compliance; then follow-up consultations will be conducted by the ophthalmologist in regular schedule (see Table 1) over the 18-month period to review the condition and to deliver other supplies of eye drops. Each ophthalmological consultation will last for about 30 minutes;

5. for those allocated in the DIMS-treatment group, you will be arranged to have the consultation by an optometrist at the Optometry Clinic of HK Polytechnic University for the prescription of a pair of DIMS lens spectacles (see Table 2). You and your child should fill the e-logbook given for the record of compliance. The consultation for delivery of DIMS spectacles will last for about 30 minutes;

6. follow-up eye examinations for each subject in both groups 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;

7. your child in the atropine-treatment group will attend total 5 consultations by ophthalmologist and total 5 consultations by optometrist over 24 months;

8. your child in the DIMS-treatment group will attend total 6 consultations by optometrist over 24 months.

Schedule of visits

Table 1. Atropine-treatment group

1st visit	Comprehensive eye check and electrophysiological measurement
2nd visit	Follow-up Comprehensive eye check and electrophysiological measurement
3rd visit	1st Consultation by Ophthalmologist and receiving 3-month eye drops
4th visit	2nd Consultation by Ophthalmologist and receiving 3-month eye drops
5th visit	Follow up eye check and electrophysiological measurement
6th visit	4th Consultation by Ophthalmologist and receiving 6-month eye drops
7th visit	Follow up eye check and electrophysiological measurement
8th visit	5th Consultation by Ophthalmologist and receiving 6-month eye drops
9th visit	Last follow up eye check and electrophysiological measurement
10th visit	Last consultation by Ophthalmologist

Table 2. DIMS-treatment group

1st visit	Comprehensive eye check and electrophysiological measurement
2nd visit	Follow-up Comprehensive eye check and electrophysiological measurement
3rd visit	Delivery of DIMS spectacles
4th visit	Follow up eye check and electrophysiological measurement
5th visit	Follow up eye check and electrophysiological measurement
6th visit	Last follow up eye check and electrophysiological measurement

Venue:
Ophthalmological consultation: Eye clinic, Grantham Hospital
Optometric consultation (including follow-up and electrophysiological measurement): Optometry Clinic, HK Polytechnic University

Procedure for special retinal function (electrophysiology) 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, 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?

Benefit:

Your child who fit for the inclusion criteria can receive a series of eye examinations over 24 months performed by a registered optometrist in which the required fee will be covered by this project. Also, children who successful joined this project will receive either drug or lens treatments for myopia control.

Risks:

The risks are minimal. Your child will be instilled with 2 drops of 1.0% Cyclopentolate which is common diagnostic eye drop used in general ophthalmic practice for accurate assessment of refractive status and eye health for children. This eye drop 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 angle of anterior

part of eyeball 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 18-24 hours in which your child may experience blur at near and very sensitive to light (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 18-24 hours in which your child may experience blur at near and very sensitive to light (photophobia) during this period.

In this study, a very low concentration of atropine (0.05%) will be used as myopia control treatment and be given to the subjects in the atropine-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 0.05% 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. If your child has noticed to have the above signs and symptoms, you can contact our optometrist immediately and we will arrange for your child to visit the ophthalmologist. Our team will determine the situation and will decide if your child should suspend or withdraw from the study.

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. Bonnie Choy (Ophthalmologist) during office hours or Dr. Kai Yip Choi (Optometrist) both office and non-office hours if you have any problems of your child after instilling the eye drops. If your child has any adverse conditions, you can consult any medical doctor or visit the Accident and Emergency (A&E) Department of Government Hospitals immediately.

The DIMS lens has been launched in the market since 2019 and there is not side effect reported Hence, wearing the DIMS spectacles should not result in any undue discomfort. If your child has noticed to have any discomfort in using the spectacles, you can contact our optometrist immediately and we will arrange for your child to visit the optometrist. Our team will determine the situation and will decide if your child should suspend or withdraw from the study.

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 Prof Henry Chan (Tel: 2766 7937, email: henryhl.chan@polyu.edu.hk) or Dr. Kaiyip Choi (Tel: 3400 2934, email: kaiyip.choi@polyu.edu.hk) (Project contact number: 51740672) for any questions you have. They will answer all questions you have.

Confidentiality

The information you provide as part of the project is the research data. Any research data from which you and your child can be identified are known as personal data. Personal data does not include data where the identity has been removed (anonymous data). We will minimize our use of personal data in the study as much as possible. The researcher and his team, supervisor, collaborator will have access to personal data and research data for the purposes of the study. The PolyU IRB and HKU/HA HKW IRB are authorized parties to access subjects' records related to the study for ethics review purpose. Responsible members of the IRBs may be given access for monitoring and/or audit of the research.

All information related to you and your child will remain confidential and all the subjects will be identifiable by codes only known to the researchers. The information collected will be stored securely and kept for 7 years after completion of the project. Raw data will also be destroyed 7 years upon the completion of this project. PolyU takes reasonable precautions to prevent the loss, misappropriation, unauthorized access or destruction of the information you provide.

Thank you for participation of your child.

In the event you have any complaints about the conduct of this research study, you may contact Secretary, PolyU IRB (institutional.review.board@polyu.edu.hk) or HKU/HA HKW IRB (hkwirb@ha.org.hk) in writing stating clearly the responsible person and department of this study as well as the Reference Number.