PARTICIPANT INFORMATION SHEET – Parent/Guardian

Interventional Study - *Parent/Guardian consenting on behalf of participant*

Project title: WA ATOM pilot study: Atropine for the treatment of myopia

Project sponsor: Lions Eye Institute

Principle Investigator: Professor David Mackey.
Associate Investigators: Professor Geoffrey Lam, Dr Antony Clark
Location: Lions Eye Institute, Nedlands WA 6009 Tel: 08 9381 0777

1. What does my child's participation involve?

Your child has been tested over the previous year by an optometrist or an ophthalmologist and identified as having early onset myopia (also known as short-sightedness) and may be eligible to take part in this study.

Myopia develops when the eyes become slightly elongated, more egg-shaped or less round. This causes them to have better vision close up for reading but distance vision is blurred.

Myopia can be corrected by wearing glasses however this will not prevent the condition from progressing. Myopia can lead to more serious sight threatening conditions such as raised pressure within the eyes (also known as glaucoma) or problems involving the retina at the back of the eye which can lead to blindness.

You and your child are invited to take part in this research project that will test a new treatment to control the progression of myopia. The treatment is an eye drop called Atropine.

This Participant Information Sheet tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want your child to take part in this research study.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not your child can take part, you might want to talk about it with a relative, friend or your child's local doctor.

Participation in this research project is voluntary. If you do not wish your child to be part of the study, they do not have to. Your child will receive the best possible care whether or not they take part.

If you decide you want your child to take part in the study, you will be asked to sign the consent form. By signing it you are telling us that you:

• Understand what you have read

• Consent to your child taking part in the research project

• Consent for your child to have the tests and treatments that are described

• Consent to the use of your child's personal and health information as described.

You will be given a copy of this Participant Information and the Consent Form to keep.

2. What is the purpose of this research?

The aim of this study is to test whether a very dilute (0.01%) solution of a muscle relaxing medication (Atropine) given as a single daily eye drop, can slow the progress of myopia. The treatment part of the study will run for 2 years.

In order to test how well the treatment works, two thirds (66%) of the children will receive the Atropine eye drops and one third (33%) will receive eye drops that do **not** contain the active ingredient atropine - these eye drops are called 'a placebo'. All children will be randomly assigned to either the atropine (treatment group) or to the placebo (no treatment) group.

Medications, drugs and devices have to be approved for use by the Australian Federal Government. Atropine is an approved medicine in Australia, for the treatment of other eye problems in children. This trial will use atropine eye drops in a more dilute (weaker) solution (100 times weaker) on a daily basis, for 2 years.

This research project is funded by a grant from Telethon – Perth Children's Hospital Research Fund.

3. What does participation in this research involve?

Steps to joining the study:

- Your own optometrist or eye specialist will discuss how to manage your child's developing myopia whenever you have regular vision check-ups.
- If you are interested in taking part in this trial of atropine eye drops to reduce the effect of myopia on your child's vision, your optometrist will provide further information (Recruitment letter) and forward your contact details to the study co-ordinator.
- You can choose to attend a recruitment appointment at the Lions Eye Institute by emailing the Lions Eye Institute or by completeing and returning the slip attached to the Recruitment letter.
- The study co-ordinator will then contact you to arrange an appointment at the Lions Eye Institute.
- Attend an assessment appointment at Lions Eye Institute (2 hours).
- Complete the consent form after you have read this Information Sheet.
- Your child will have eye or vision assessments (reading chart), photographs and other eye measurements taken
- Complete the family profile form. This will collect data on your child's age, ethnic background, place of birth, time living in Western Australia and, if known, whether there is a family history of myopia.
- As a parent we will also measure your own vision using the same methods and machines as used for your child.
- This is a randomised controlled trial. This means that it will not be known which treatment your child will receive; the study co-ordinator and doctor will also not know.
- There will be 2 groups in this trial, one group will receive atropine 0.01% eye drops and the other group will be allocated to the control group and will receive placebo/neutral eye drops. (A placebo is a medication with no active ingredients. It looks like the real thing but is not.)
- The eye drops will be administered each day, at bedtime. One drop per eye every day.
- Activity diary over the 2 years of the treatment: Each child will be issued with a diary to record daily and weekly estimates of time spent:
  a) studying, reading, watching TV or computer based screen activities,
  b) walking/playing/sport outdoors

c) playing/sport indoors
This can be completed on paper or directly on-line, once per week.

- Every 6 months over the 2 years trial period your child will return to the Lions Eye Institute for eye measurements and vision testing. The eye drops will be provided free of charge at each visit.
- There are no costs associated with participation in this research project, nor will you be paid. All medications, tests and medical care required as part of the research project will be provided to the child free of charge.

We have included a map and information on how to get to the Lions Eye Institute, and where to park. We can provide evening and weekend appointments outside of normal clinic hours, if required. The total time for this initial assessment is about 2 hours.

4. What does my child have to do?

Being part of this study will not require any changes to normal activities, other than the application of the eye drops each evening at bedtime. We would not expect your child to modify their activities during the study. The eye drops will not interfere with any other medications.

5. Other relevant information

This pilot study will involve 54 children in total, 36 will be receiving 0.01% atropine eye drops and 18 will receive placebo eye-drops that do not contain any atropine over a 2 year treatment period. All children will be assessed at Lions Eye Institute. At the end of the treatment phase, if the analysis demonstrates that the 0.01% atropine eye drops were beneficial the consent will be sought from the Human Research Ethics Committee to offer all children who completed 24 months of placebo eye drops an option to receive a complementary 12 month supply of eye drops containing the 0.01% atropine.

6. Does my child have to take part in the research project?

Participation in this research project is voluntary. If you decide that they can take part and later change your mind, you are free to withdraw your child from the project at any stage.

7. What are the alternatives to participation?

During the consent process, the researchers will discuss the options available for the control of myopia such as; glasses, increased time outdoors or orthokeratology with hard contact lenses.

8. What are the possible benefits of taking part?

We cannot guarantee that your child will receive any benefits from this research. However, by participating in this research project you will be helping to increase knowledge and understanding of myopia development, its causes and possible treatment options.

9. What are the possible risks and disadvantages of taking part?

Medical treatments can have side effects. Your child may have none, some or all of the effects listed below, and they may be mild, moderate or severe. If your child has any of these side effects, or you are worried about them, talk with the study doctor. The study doctor will also be looking out for side effects during the visits.
The eye drops used in this study may cause:
- increased sensitivity to bright-light
- blurred vision
- local eye redness or irritation

If a serious side effect occurs (making them ill or causing vision problems) relating to the eye drop treatment, it should be reported immediately to the study co-ordinator. A clinical review by the study doctor will be arranged, and options for the continuation/cessation of treatment discussed.

10. What happens if we miss a dose or if we give too much?

If you forget or miss a dose of eye drops, for any reason, just record this in the diary and resume daily drops the following day. If you accidently add more than one eye drop or more than the recommended dose just record this in the diary, and resume normal eye drops the following day.

11. What if new information arises during this research project?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, the study doctor will tell you about it and discuss with you whether you want your child to continue in the research project. If you decide to withdraw your child from the study we will make arrangements for their regular eye care to continue. If you decide that the child can continue in the research project, you will be asked to sign an updated consent form.

12. Can my child have other treatments during this research project?

It is important to tell the study doctor and the study staff about any treatments or medications your child may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also tell the study doctor about any changes to these during your child's participation in the research project. These can also be recorded in the study diaries.

13. What if I withdraw my child from this research project?

If you decide to withdraw your child from the project, please notify a member of the research team. This notice will allow the research co-ordinator to further discuss any health risks or special requirements linked to stopping the treatment/eye drops. Withdrawing from the study will not affect your child's on-going medical care.

14. Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons. These include reasons such as:
• Unacceptable side effects
• The drug/treatment is shown not to be effective
• The drug/treatment is shown to work and not need further testing
• Decisions made by local regulatory/health authorities.

15. What happens when the research project ends?

The provision of eye drops will cease after the initial 24 months treatment period. We will continue to monitor your child's vision for a further 12 months after the treatment period ends.

After analysis of the study results we may recommend that you and your child commence, continue or stop atropine eye drop treatment. If no benefit is demonstrated by this study treatment we will inform you of this finding. The results of the study will be published in peer reviewed journals and presented at stake-holder conferences and meetings. A summary report will be sent to all participating children and their families.

16. What will happen to information about your child?

All stored data relating to study participants will be non-identifiable (coded with Study ID numbers and Date of Birth) and will remain confidential. All data will be stored on secure, password protected databases, backed-up on computers within the Lions Eye Institute. Only staff approved by the Chief Investigator will have access to the data for analysis.

Your child's information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

17. Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the Princess Margaret Hospital HREC. This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007). If you have any concerns and/or complaints about the project, the way it is being conducted or your child's rights as a research participant, and would like to speak to someone independent of the project, please contact:
The Executive Director of Medical Services at PMH on 9340 8222.
Your concerns will be drawn to the attention of the Ethics Committee who is monitoring the study.

18. Further information and who to contact

If you want any further information concerning this project or if the participant has any medical problems which may be related to their involvement in the project (for example, any side effects), you can contact the principal study doctor: Professor David Mackey or the following people:

Clinical contact person

Name	
Position	Study co-ordinator
Telephone	9381 0777
Email	xxxxxxxx@lei.org.au

For matters relating to research at the site at which the child is participating, the details of the local site complaints person are:

Complaints contact person

Name	Tracey Dickens
Position	Clinical Research Manager
Telephone	9381 0829
Email	traceydickens@lei.org.au

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

The Executive Director of Medical Services at PMH on 9340 8222.
Your concerns will be drawn to the attention of the Ethics Committee who is monitoring the study.