

2.

INFORMATION LEAFLET + ASSENT FOR 6-16 YEAR OLD PARTICIPANTS

RESEARCH TITLE: Myopia Outcome Study of Atropine in Children



MOSAIC
Myopia Outcome Study of Atropine In Children

Please read carefully. If there is anything that you don't understand, please ask one of your parents to explain.

- Myopia (shortsightedness) makes objects in the distance, such as the whiteboard in school or the television, look blurred. This is caused by your eyes growing too long, something that usually happens while you are also getting taller.
- We can correct myopia with glasses or contact lenses, but we don't treat people to stop their eyes needing stronger glasses as they grow.
- The MOSAIC trial is investigating a type of eye drop that might help to stop myopia getting worse year by year. This may help to prevent your eyesight without glasses getting too bad, and also keep your eyes healthier as you get older.

The study will be conducted by Prof Flitcroft and Prof Loughman at the **Centre for Eye Research Ireland (CERI)**, which is part of the Dublin Institute of Technology, Grangegorman Campus Grangegorman Lower, Dublin 7. We are recruiting 250 myopic children for this study.

Study Design

In this trial we will be comparing eye drops that contain an ingredient that we think will help to slow down myopia (atropine 0.01%) with eye drops that are only designed to keep eyes moist (placebo eye drops). This is the best way to see if atropine really works. Everyone in the trial will be randomly chosen to have either the atropine or placebo eye drops. Most will get the atropine eye drops (167 people) and a smaller number (83 people) will get the placebo. The drops, which don't sting or blur your vision, will need to be put into each eye every evening.

After two years the people who get the placebo drops will also get the choice to use the atropine drops for a year, so everyone in the trial has a chance to take the drops that we expect to slow down the progression (worsening) of myopia.

Each participant will visit the Centre for Eye Research Ireland a minimum of 8 occasions. This will include a pre study visit to check for eligibility 6 months before the baseline visit, the baseline visit followed by a visit at 6, 12, 18, 24, 30 and 36 months.

What happens at the study visits?

April 2019

- At the first study visit the parent/guardian will be asked to sign an informed consent form, and each participant will be asked to sign an agreement (assent) form.
- The parent/guardian will be asked to complete a brief questionnaire about family history of myopia and their child's daily lifestyle (information about things like reading, sports, computer use and time spent outdoors).
- A series of routine eye tests will be performed eg visual acuity, reading speed, pupil diameter.
- All subjects will be given eye drops (cyclopentolate hydrochloride 0.5%) in both eyes, this will relax the muscles in the eyes in order to accurately calculate the subject's glasses prescription.
- The eye will be measured with a device that works without touching your eye
- The health of the eye will be assessed with a comprehensive examination, similar to a test you would get at an eye clinic or optometrist.
- Feedback will be given at the end of the trial in relation to the progression of myopia

Possible side effects/risks of long term use of atropine

The following side effects are possible from the long-term use of 0.01% atropine.

- An increase in pupil size (which may cause glare) and a lesser ability to accommodate (which may lead to difficulty reading up close). However with the diluted low dose of atropine used in this trial the risk of glare and reading difficulty is minimised
- Other, less common and rare adverse effects of atropine include irritation, conjunctivitis, increased intraocular pressure, and swelling of the eyelids. Participants and parents will be provided with information describing the clinical signs of the above side effects, and given appropriate instruction as to appropriate management in each case.

Storage, retention and destruction of clinical trial data (your information)

- We will take great care to ensure that any information we collect is stored safely. In computer files that contain information about you're your family and your eyes, you will identified only by an identification number. Your name and any other identifying detail will not be included in these files.
- The information we collect will be kept for five years to allow us to analyse the data. Once that is done the information we have on computer and on paper will be safely deleted or destroyed.

What happens to the eye drop bottles after use?

The eyedrop bottles should be returned to the study investigators at your next visit.

ASSENT FORM

Reference Number:	Protocol Number:
Title of Research Study: Myopia Outcome Study of Atropine in Children (MOSAIC)	
Participant Name:	
Name of Optometrist and Telephone Number:	

To be completed by the participant

Once you become short sighted (need glasses to see clearly at a distance) your glasses will usually need to be increased every year for many years. We currently have no way to stop or slow down this process. We are asking you to take part in a research study to find out if an eye drop can stop your eyes from becoming more and more shortsighted. If you agree to take part in the study you (or a parent/guardian) will put an eye drop into both eyes each night before bed for 2 years. You will be asked to return to DIT every 6 months for a check up. At each check up we will measure the length of your eye, check your vision and check the health of your eye. Before you sign this, make sure you have asked any questions you might have and understand what is involved.

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Name of Participant (in block letters)	Date	Signature
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Assent Given

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Optometrist/Researcher	Date	Signature
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1 copy for participant, 1 copy for researcher.

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