

Effects of pupil-dilating drug on myopia progression and intraocular pressure elevation

Submission date 19/01/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 31/05/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 30/11/2020	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Short-sightedness, or myopia, is a common eye condition resulting in distant objects appearing blurred to the sufferer. The condition usually starts from around puberty, but can develop in younger children. The condition gradually gets worse over time. It is caused by the eye stretching and becoming slightly longer than it should. This means that light does not focus on the retina (light-sensitive tissue) of the eye but just in front of it, causing far away objects to look blurred. Myopia is associated with an increase in pressure within the eye (intraocular pressure) over a long period of time. Some studies have shown that the drug atropine slows down the progression of myopia. This study looks at the effects of topical atropine (atropine given as eye drops) on the intraocular pressure of the eye and myopia progression in children and aims to find out the smallest amount of drug that needed (lowest concentration) to get results.

Who can participate?

Short-sighted children aged between 6 and 12 and living in Northern Taiwan.

What does the study involve?

Children are assigned to one of three groups. If the parents state a preference for the child not to be treated with medication, they are assigned to the control group and given glasses to correct their vision if required. If the parents state a preference for their child to be treated with medication, they are randomly allocated to one of two groups. Children in group 2 are given eye drops containing 0.125% atropine in addition to corrective glasses if required. Children in group 3 are given eye drops containing 0.25% atropine in addition to corrective glasses if required. Myopia progression and intraocular pressure is measured at the start of the study and then every 3 months for the next 12 months for all participants.

What are the possible benefits and risks of participating?

In general, there is almost no risk for taking part in this study because atropine use in Taiwan is routine and general practice for myopic children. The only risk, if any, is that those who did not use atropine (control group) will run a rapid myopic progression speed and have a greater chance of high myopia and associated complications during their late adult life.

Where is the study run from?
Chang Gung Memorial Hospital (Taiwan)

When is the study starting and how long is it expected to run for?
March 2009 to March 2011

Who is funding the study?
Chang Gung Medical Research Foundation

Who is the main contact?
Dr Chi-Chin Sun

Contact information

Type(s)
Scientific

Contact name
Dr Chi-Chin Sun

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Effects of topical atropine on intraocular pressure and myopia progression

Study objectives
Topical atropine has been used for a long time to control myopia progression. However, the minimal effective concentration has not been established. Moreover, its effect on intraocular pressure is still in debate. Therefore, we conducted this prospective study.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Institutional Review Board at Chang Gung Memorial Hospital, Taiwan, 30/01/2009, ref: 97-1988A3

Study design

Single site prospective, interventional longitudinal and non-randomized study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Myopia in children

Interventions

This is an interventional study that enrolled children with myopia. If the parents state a preference for their child to not receive any medications, they are assigned to the control group with spectacles correction if needed.

If their parents state a preference for their child to be treated with medications, the child is randomly assigned to one of two groups:

1. Child is treated with 0.125% atropine in addition to spectacle correction
2. Child is treated with 0.25% atropine in addition to spectacle correction

All children are followed up for the next 12 months.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Atropine

Primary outcome measure

Myopia and its progression: with autorefractometer and manifest refraction by experienced technician. Assessed at baseline and then every 3 months for next 12 months.

Secondary outcome measures

IOP measurement: with pneumatic tonometer by experienced technician. Assessed at baseline and then every 3 months for next 12 months.

Overall study start date

01/03/2009

Completion date

01/03/2011

Eligibility

Key inclusion criteria

1. Children in Northern Taiwan aged between 6 to 12 years.
2. Patients with a refractive error less than -3.0 diopters (D)

Participant type(s)

Patient

Age group

Child

Lower age limit

6 Years

Upper age limit

12 Years

Sex

Both

Target number of participants

60 children

Total final enrolment

56

Key exclusion criteria

1. Congenital eye disorder
2. Any disease influence the cornea, lens or retina
3. Best correct visual acuity < 20/25 using the Snellen chart
4. Primary intraocular pressure above 21mmHg
5. Atropine application within 6 months before enrollment
6. Patients who could understand the details of this study or could not adhere to the follow up schedule

Date of first enrolment

01/05/2009

Date of final enrolment

31/12/2010

Locations

Countries of recruitment

Taiwan

Study participating centre

Chang Gung Memorial Hospital

Keelung

Taiwan

204

Sponsor information

Organisation

Chang Gung Memorial Hospital

Sponsor details

6F, Department of Ophthalmology

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204

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/02verss31>

Funder(s)

Funder type

Research organisation

Funder Name

Chang Gung Medical Research Foundation

Results and Publications

Publication and dissemination plan

This manuscript has been submitted to BMC Ophthalmology and currently under consideration for publication. If possible, we expected it will be published within 3 months. The dissemination targets are those who are interested in myopia control and concern about side effects of mydriatics, including professional Ophthalmologists, public health researchers and the general public.

Intention to publish date

31/07/2016

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	19/07/2016	30/11/2020	Yes	No