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

Submission date	Recruitment status	[_] Prospectively registered
19/01/2016	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
31/05/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
30/11/2020	Eye Diseases	

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
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Additional identifiers

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

Study type(s)
Treatment

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

Key secondary outcome(s))
IOP measurement: with pneumatic tonometer by experienced technician. Assessed at baseline and then every 3 months for next 12 months.

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

Healthy volunteers allowed

No

Age group
Child

Lower age limit
6 years

Upper age limit
12 years

Sex
All

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

ROR
https://ror.org/02verss31

Funder(s)

Funder type
Research organisation

Funder Name
Chang Gung Medical Research Foundation

Results and Publications

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