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Drug effects on blood pressure, heart rate, and eyes in children with refractive error

Submission date
20/10/2022

Recruitment status
No longer recruiting

Registration date
25/10/2022

Overall study status
Completed

Last Edited
25/10/2022

Condition category
Eye Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The aim of this study is to compare the effectiveness of a combination of cyclopentolate eye drops 1% and phenylephrine 2.5% with and without tropicamide 1% in reducing the effect of eye accommodation and widening pupil diameter in children with refractive error (a type of vision problem that makes it hard to see clearly).

Who can participate?
Patients aged 6-18 years who have mild to moderate refractive error

What does the study involve?
Participants are randomly allocated to one of two drug combinations, namely the combination of cyclopentolate 1%, tropicamide 1%, and phenylephrine 2.5% and the combination of cyclopentolate 1% and phenylephrine 2.5%. Participants receive one drop of topical anesthetic in both eyes. Five minutes later, a drop of the drug combination is given in both eyes as much as one drop at 5-minute intervals. An eye test is carried out before the administration of the drug, as well as at the 20th, 30th, 45th, and 60th minutes after the first administration of the drug combination.

What are the possible benefits and risks of participating?
The possible benefits of participating in this study are obtaining data regarding the condition of the eyeball, more accurate eyeglass correction, and easier access to children's eyeglass services. The results of the study can be used as recommendations in the standard administration of drugs for the examination of eye abnormalities in children. Information regarding the results of the eye examination and research conclusions will be provided by the researcher at the end of the examination and at the end of the study.
The examination that will be carried out may cause a little discomfort, such as a stinging feeling when the drug is administered, but this can be minimized by giving a topical anesthetic before the drug. Superficial corneal inflammation and redness of the mucous membrane of the eye may occur but can be treated with eye drops. Other risks are dryness of the skin and mucous membranes, increased blood pressure, temperature, or heart rate, heart rhythm irregularities,

and central nervous disorders such as impaired consciousness, slurred speech, or seizures. However, these are very rare and are treated by pressing the inner corner of the eye to reduce the absorption of the drug into the body.

Where is the study run from?
Cicendo National Eye Hospital (Indonesia)

When is the study starting and how long is it expected to run for?
March 2020 to May 2021

Who is funding the study?
Cicendo National Eye Hospital (Indonesia)

Who is the main contact?
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Contact information

Type(s)
Principal investigator

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Additional identifiers

Study information

Scientific Title
Does the usage of cyclopentolate, phenylephrine, and tropicamide compare with cyclopentolate and phenylephrine give more ocular and systemic effects in children with refractive error?

Study objectives
1st hypothesis: Changes in refractive power after administration of a combination of 1% cyclopentolate, 1% tropicamide, and 2.5% phenylephrine were the same when compared with the combination of 1% cyclopentolate and 2.5% phenylephrine in children with refractive errors.

2nd hypothesis: Changes in pupil size after administration of a combination of 1% cyclopentolate, 1% tropicamide, and 2.5% phenylephrine were the same as after the combination of 1% cyclopentolate and 2.5% phenylephrine in children with refractive errors.

3rd hypothesis: Changes in blood pressure between the administration of a combination of 1% cyclopentolate, 1% tropicamide, and 2.5% phenylephrine were the same when compared to the combination of 1% cyclopentolate and 2.5% phenylephrine in children with refractive errors.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 19/10/2020, Kementerian Pendidikan dan Kebudayaan Universitas Padjadjaran Research Ethics Committee (Jl. Prof Eyckman No. 38 Bandung 40161, Indonesia; +62 (0)22 2038697; etik.unpad@gmail.com), ref: 985/UN6.KEP/EC/2020

Study design
Single-blind randomized clinical trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Refractive error

Interventions
This study is a single-blind randomized clinical trial with a parallel design to compare the ocular effects (changes in refractive power and size of pupillary dilatation) and systemic effects (changes in blood pressure and heart rate) of the combined administration of 1% cyclopentolate, 1% tropicamide, and phenylephrine 2.5% (SFT) compared with the combination of 1% cyclopentolate and 2.5% phenylephrine (SF) in children with refractive errors. Determination of the treatment group is done by block randomization based on the order of the envelope which already contains the name of the drug regimen which is adjusted to the order of arrival of the patient. Determination of the contents of the envelope is based on a random system that has been used previously. Subjects will be given information about the type of drug given. Refractive power and pupil diameter are measured using an autorefractometer and IOL Master®700. Blood pressure and heart rate are examined before and 60 minutes after drug administration.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Cylopentolate, phenylephrine, tropicamide

Primary outcome(s)
Refractive power measured using autorefractometry and IOLMaster®700 examination in both eyes at 60 minutes after administration of the first drops of the combination drug regimen.

Key secondary outcome(s))
Blood pressure and heart rate measured using Omron Automatic Blood Pressure HEM 7120 at 60 minutes after administration of the first drops of a combination drug regimen

Completion date
30/05/2021

Eligibility

Key inclusion criteria
Children 6-18 years of age who had mild to moderate refractive errors before administration of cycloplegic agents (myopia <6.00 D, hyperopia <3.00 D, and astigmatism <3.00 D)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 years

Upper age limit
18 years

Sex
All

Total final enrolment
54

Key exclusion criteria
1. Visual disturbances unrelated to refractive errors, such as corneal opacities, uveitis, glaucoma, cataracts, posterior segment disorders, and disorders of the optic nerve/visual pathway
2. History of ocular surgery
3. Pupillary abnormalities or other neurological disorders
4. History of cardiovascular disease
5. Receiving systemic or ocular medical therapy that affects pupil function and/or accommodation
6. High anisometropia (difference in eye refractive status ≥2.00 D)
7. Strabismus, amblyopia
8. Light colored iris (green or blue iris)
9. Albinism

10. History of allergy to the components of the research drug
11. Children who were not cooperative during drug administration, did not complete autorefractometer and pupil diameter measurements, or developed adverse drug reactions after administration of the regimen

Date of first enrolment
01/11/2020

Date of final enrolment
31/03/2021

Locations

Countries of recruitment
Indonesia

Study participating centre
National Eye Center Cicendo Eye Hospital Bandung
Jl. Cicendo No.4
Babakan Ciamis
Kec. Sumur Bandung
Kota Bandung
Jawa Barat
Bandung
Indonesia
40117

Sponsor information

Organisation
Research Unit of Cicendo National Eye Hospital

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Research Unit of Cicendo National Eye Hospital

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to subjects' confidentiality and privacy.

IPD sharing plan summary
Not expected to be made available