

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

Submission date 20/10/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 25/10/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 25/10/2022	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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?

Irawati Irfani, irawati.irfani@unpad.ac.id

Contact information

Type(s)

Principal Investigator

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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

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)

Cyclopentolate, phenylephrine, tropicamide

Primary outcome measure

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.

Secondary outcome measures

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

Overall study start date

19/03/2020

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

Age group

Child

Lower age limit

6 Years

Upper age limit

18 Years

Sex

Both

Target number of participants

54 patients (108 eyes)

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

Sponsor details

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Sponsor type

Hospital/treatment centre

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Research Unit of Cicendo National Eye Hospital

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

10/11/2022

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