A double blind randomized study on the efficacy of cyclopentolate 1% and cyclopentolate 1% with tropicamide 1% in children

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To compare one dose of the short acting tropicamide combined with one dose of the longer acting cyclopentolate (c+t) with a double dose of the longer acting cyclopentolate (c+c). To develop a cycloplegics protocol that garantees optimal refractieve...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Vision disorders
Study type	Interventional

Summary

ID

NL-OMON34025

Source
ToetsingOnline

Brief title
Efficacy of cycloplegics

Condition

- Vision disorders

Synonym
Cycloplegia. Inhibition of accommodation

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Haaglanden

Source(s) of monetary or material Support: Zorgvernieuwing (zorgverzekeraars)

Intervention

Keyword: Astigmatism, Cycloplegia, Mydriasis, Recuperation time, Residual accommodation

Outcome measures

Primary outcome

Primary outcome parameters are residual accommodation; e.g. depth of cycloplegia (survey I) and recuperation time of ciliary paralysis (survey II) and sphincter paralysis (survey III). Differences will be considered statistical significant if $p<0.05$. A difference in residual accommodation of > 0.50 D, a difference in recuperation time of > 2 hours of cycloplegia and pupillary functions, will be considered clinical significant.

Secondary outcome

Survey I

Secondary outcome parameters are 1) time to maximum cycloplegia, 2) time of stability of (maximum) cycloplegia and 3) changes in astigmatism. Differences will be considered statistical significant if $p<0.05$. A difference in time to maximum cycloplegia of > 10 minutes, a difference in stability time of > 10 minutes, and a change of > 0.50 D cylinder or a change of >5° in cylindrical axis will be considered clinical significant.

Study description

Background summary

Tropicamide is less effective in inhibiting accommodation and has a small window of maximum activity. Cyclopentolate is more effective but in darker

pigmented subjects a significant residual accommodation can be present.

Children often show resistance against the adminisatrion of cyclopegic eyedrops. Sqeezing of eyelids and/or crying with hyperlacrimation provide a smaller amount of- or diluting of cycloplegics. A smaller amount of cycloplegic(s) might cause insufficient cycloplegia. Insufficient cycloplegia interferes, especially in darker pigmented subjects, with refractive outcomes. Scientific literature currently does not provide an answer on efficacy and reliability of cycloplegics in the presence of squeezing and/or dilution.

Time might be an important aspect in reliability of outcomes. On a regular base there is delay during consultation. In tropicamide, the time where in reliable measurements can be made, especially in darker pigmented individuals or in case of squeezing or dilution, is not known.

Amount of mydriasis and/or pupillary reaction to light might be predictors of sufficient cycloplegia. Scientific literature currently does not provide an answer on this possible relationship.

Cycloplegia interferes with normal daily life. We could not find reports which investigated this interference, the subjective wellbeing of children after cycloplegics and the time course of recuperation of ciliary- and sphincter paralysis.

Study objective

To compare one dose of the short acting tropicamide combined with one dose of the longer acting cyclopentolate (c+t) with a double dose of the longer acting cyclopentolate (c+c). To develop a cycloplegics protocol that garantees optimal refractieve outcomes, incorperates factors such as pigmentation, resistance and quality of life.

Study design

This investigator initiated study is designed as a prospective, single-centre, cross sectional, quantitative, randomized double blind trial with repeated measurements.

The study is divided in three parts. Survey I measures residual accommodation; e.g. depth of cycloplegia, time to maximum cycloplegia, and stability of (complete) cycloplegia in time. Survey II measures (monitors) recuperation of cycloplegia in time and survey III measures (monitors) recuperation of mydriasis and pupillary motor function in time.

Duration of the study is approximately 6 months; until 137 subjects completed the measurements of survey I, 141 subjects completed the measurements of survey

II and 141 completed the measurements of survey III.

Intervention

Randomized
* Two doses of cyclopentolate hydrochloride 1%; with an interval of 5 minutes in both eyes
or
* One dose of cyclopentolate hydrochloride 1% followed by one dose tropicamide 1%; after an interval of 5 minutes,
in both eyes

Study burden and risks

RISKS
There are no additional risk*s present since subjects are already planned for a routine cycloplegic refractive assessment according to their treatment or standard departmental follow-up.

BURDEN
Duration of a standard visit is 75 minutes
Duration of a study visit is:
Survey I : 115 minutes; the extra time added to the standard visit will be 40 minutes
Survey II : 85 minutes; the extra time added to the standard visit will be 10 minutes
Survey III : 75 minutes: no extra time

The extra activities e.g. effort needed because of the study are
Survey I : 5 times a non invasive, simple measurement with a duration of 5-10 seconds
: 5 times a non invasive, simple measurements with a duration of 3 minutes

Survey II : 5 times a non invasive, simple measurement with a duration of 5-10 seconds
: 1 time a non invasive, simple measurements with a duration of 3 minutes
: at daytime for 12 to 24 hours, hourly 1 non invasive,
simple measurement with a duration of maximal 2 minutes

Survey III : 5 times a non invasive, simple measurement with a duration of 5-10 seconds
: at daytime for 12 to 24 hours, hourly 1 non invasive,
simple measurement with a duration of maximal 2 minutes

The extra measurements provide a small burden. Measurements normally are experienced as amusing due to the images displayed in the devices. All measurements are done by non-contact devices. Main measurements will be performed 5 times; with and interval of 15 minutes, and will take 3 minutes each. The five short measurements will be performed between entry and 50 minutes after the first eye-drop and will take 5 second each. Between measurements the patients will have the opportunity to play. Inconvenience will mainly consists of the extended time period of the appointment in survey I, and the prolonged time of short hourly measurements during 12 to 24 hours in survey II and III.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

Healthy, light to very dark irided, 7 to 13 years old volunteers, visiting group 4 to 8 of the Dutch primary school system. In addition to be included in survey I and II, children should be hypermetropic; whether or not wearing glasses, with normal accommodation, sufficient reading capabilities and a best corrected visual acuity for distance of ><=0.7 and near of ><=1.0. To be included in survey III children should be emmetropic or myopic, have pupils that are equal in size and react normally.

Exclusion criteria

Physical illness, aged <7 and >13 year, attending group 3 of the Dutch school system or attending secondary school. For survey I and II refractive errors < +0.50D with or without glasses, insufficient accommodation, insufficient reading capabilities, best corrected distance visual acuity of < 0.7 and near visual acuity of <1.0. For survey III having hypermetropia, unequal pupil sizes or abnormal pupillary reactions.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-10-2010
Enrollment:	419
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	unit dose® cyclopentolate hydrochloride 1%; 10 mg/ml
Generic name:	cyclopentolate hydrochloride 1%; 10 mg/ml
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	unit dose® tropicamide 1%; 10mg/ml
Generic name:	tropicamide 1%; 10mg/ml
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	06-07-2010
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	12-08-2010
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 21701

Source: NTR
Title:

In other registers

Register	ID
EudraCT	EUCTR2010-021410-34-NL
CCMO	NL32954.098.10
OMON	NL-OMON21701