Een dubbelblind gerandomiseerd onderzoek naar de doelmatigheid van cyclopentolaat 1% en cyclopentolaat 1% met tropicamide 1% bij kinderen. Afkorting: Doelmatigheid van cycloplegica.

Gepubliceerd: 22-08-2010 Laatst bijgewerkt: 19-03-2025

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…

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21701

Bron
Nationaal Trial Register

Verkorte titel
Efficacy of cycloplegics

Aandoening

cycloplegia, residual accommodation, mydriasis, astigmatism, pupillary reaction to light, recupertion time.

Ondersteuning

Primaire sponsor: RvB
Medical Centre Haaglanden
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The Netherlands
Overige ondersteuning: Zorgvernieuwingsproject; Zorgverzekeraars

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

Background of the study:

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.

Objective of the study:

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 refractive 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.

Study population:

For this study all patients visiting the orthoptic department of the Medical Centrum Haaglanden, location Westeinde, requiring an objective refraction because of standard departmental protocol, meeting the inclusion criteria and who consented to take survey, until the required sample size is reached, are considered the study population.

Eligible patients should be: 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 distance visual acuity of >0.9 and near visual acuity 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.

Intervention:

Randomized:
1. Two doses of cyclopentolate hydrochloride 1%; with an interval of 5 minutes in both eyes, or;

2. One dose of cyclopentolate hydrochloride 1% followed by one dose tropicamide 1%; after an interval of 5 minutes,

in both eyes.

Primary study parameters/outcome of the study:

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.

Secundary study parameters/outcome of the study:

Survey I: Secondary outcome parameters are 1) time to maximum cycloplegia, 2) time of stability of (maximum) cycloplegi, 3) changes in astigmatism 4) mydriasis and 5) pupillary reaction to light. 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, a a difference of >0.5 mm of pupil diameter increase, a difference of 1 category pupil reaction to light in the median will be considered clinical significant.

Doel van het onderzoek

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 cyclopegics. 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. Time might be an important aspect in reliability of outcomes. Scientific literature currently does not provide an answer on efficacy and reliability of cycloplegics in the presence of squeezing and/or dilution. 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.

In this study we use a double dose of cyclopentolate 1% (c+c)and one dose of cyclopentolate 1% combined with one dose of tropicamide 1% (c+t).

The aims of this study are:

1. To investigate the depth of cycloplegia; e.g. the amount of residual accommodation, of c+c and c+t;

2. To investigate at which time maximum cycloplegia in c+c and c+t occurs;

3. To investigate the time that maximum cycloplegia is present in c+c and c+t;

4. To investigate whether c+t is as effective as c+c in:

A. Obtaining depth of cycloplegia;

B. Stability of cycloplegia; e.g. time of maximum cycloplegia.

5. To investigate whether maximum cycloplegia is different in the groups with various eye-colors in c+c and c+t;

6. To investigate whether there are differences in time at which maximum cycloplegia occurs in the groups with various eye-colors in c+c and c+t;

7. To identify factors that affect depth of cycloplegia, stability of maximum cycloplegia, mydriasis and pupillary motor functions of c+c and c+t;

8. To investigate whether the amount of mydriasis and/or pupillary motor function is associated with depth of cycloplegia;

9. To investigate whether incomplete cycloplegia affects astigmatism and to investigate factors affecting this potential relationship;

10. To investigate the recuperation time from 1) ciliary paralysis and 2) sphincter paralysis of intervention c+c and c+t;

11. To investigate whether there are differences in recuperation time of:

A. Ciliary paralysis;

B. Sphincter paralysis between c+c and c+t.

12. To identify factors that affect recuperation time form:

A. Ciliary paralysis;

B. Sphincter paralysis of c+c and c+t.

13. To investigate the subjective wellbeing of children during cycloplegia and mydriasis.

The study is devided in three parts. Survey I measures residual accommodation; e.g. depth of cycloplegia and stability of (complete) cycloplegia in time. Survey II measures (monitors) recuperation of ciliary paralysis in time and subjective welbeing during ciliary paralysis (accommodation inhibition. Survey III measures mydriasis and pupi)llary motor function, (monitors) recuperation of spincter paralysis in time and determine subjective wellbeing during sphincter paralysis (mydriasis and pupil motor inhibition).

Onderzoeksopzet

All survey's:

Prior to drops administration measurements will be made.

After drop administration for:

1. Survey I, measurements will be made at time 10, 20, 30, 40. 45, 50, 60, 75 and 90 minutes.

At time 10,20,30,40, 45, 50, 60 and 75 minutes refractive state, pupillary reaction to light will determined and amount of mydriasis measured.

At time 30,45,60,75 and 90 residual accommodation will be measured.

2. Survey II; measurements will be made at time 10,20,30,40, 45 and 50 minutes.

At time 10,20,30,40, 45 and 50 minutes refractive state, pupillary reaction to light will determined and amount of mydriasis measured.

At time 45 residual accommodation will be measured.

There after measurements; Near visual acuity, will be made (during daytime) every hour by the subjects themselves. These hourly measurements will be continued up to 2 day's. At the end of each day an questionnaire has to be filled in.

Survey III:

At time 10,20,30,40, 45 and 50 minutes refractive state, pupillary reaction to light will determined and amount of mydriasis measured.

There after measurements; Pupillary reactions to light and subjective photophobia, will be made (during daytime) every hour by the subjects themeselves. These hourly measurements will be continued up to 2 day's. Twice a day a short questionnaire has to be filled in.

Onderzoeksproduct en/of interventie

For all survey's:

Prior to measurements eye- and skin color and iris configuration (slit-lamp; irisphoto) will be individually determined by three observers/investigators.

For survey I and II the refractive state (monocular; Retinomax K+3), amount of objective (Powerrefractor II) and subjective (monocular; Zeiss-Humprey 599 and Powerrefractor II) accommodation, pupillary reaction to light (monocular; subjective by observer/investigator) and mydriasis (pupil diameter; monocular; Retinomax K+3) and near visual acuity (Dutch Radner; logmar)will be measured.

For Survey III the refractive state (monocular; Retinomax K+3), pupillary reaction to light (monocular; subjective by observer/investigator) and mydriasis (pupil diameter; monocular; Retinomax K+3) will be measured.

Measurements will be made; Right eye first; left eye second.

After these measurements cycloplegic eyedrops will be given.

For all three survey's;

Randomized, double blind:
1. 2 doses of cyclopentolate 1% with an interval of 5 minutes in each eye, or;

2. 1 dose of cyclopentolate 1% followed by 1 dose of tropicamide 1% with an interval of 5 minutes in each eye

After drop administration the measurements of survey I,II and III will be repeated (see time points).

Survey II and III will also use subjective measurements and questionnaires at home and school up to 2 days.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

General:

1. Requiring an objective refraction because of standard departmental protocol;

2. Having good general health;

3. Aged 7 to 13 years;

4. Attending group 4 - 8 of the Dutch primary school system.

Survey I and II:

1. Hypermetropia; > 0. 50 diopters in spherical equivalence (SEQ) values whether or not wearing glasses;

2. Normal accommodation; > 10 diopters with dynamic retinoscopy;

3. Sufficient reading capabilities;

4. Best corrected distance visual acuity (BCDVA) of > 0.7 in each eye;

5. Best corrected near visual acuity (BCNVA) of > 1.0 in each eye.

Survey III:

1. Emmetropia or myopia in SEQ values;

2. Isocoria and normal pupillary responses.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

General:

1. Physical illness;

2. Aged < 7 and > 13 year;

3. Attending group 3 of the Dutch school system or attending secondary school.

Survey I and II:

1. Refractive errors < +0.50 with and without glasses;

2. BCDVA of < 0.7 in one or both eye’s;

3. BCNVA of < 1.0;

4. Insufficient reading capabilities;

5. Insufficient accommodation.

Survey III:

1. Hypermetropia;

2. An-isocoria > 1mm or abnormal pupillary responses.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2010
Aantal proefpersonen:	419
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	22-08-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 34025
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2369
NTR-old	NTR2476
CCMO	NL32954.098.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON34025

Resultaten

Samenvatting resultaten
N/A