The use of neutral density filters in PlusoptiX devices.

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The software of the PlustoptiX devices is developed for pupils up to 7.8 to 8mm in size. In the study “a double blind randomized study on the efficacy of cyclopentolate 1% and tropicamide 1% in children (MEC nr NL32954.098 /1010-077; NTR 2476),...

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON25950

Bron
NTR

Verkorte titel
PlusoptiX & ND filters.

Aandoening

Pupil size. Refractive outcome. SEQ. Score of neutral density filter.

Ondersteuning

Primaire sponsor: Medisch Centrum Haaglanden.
Overige ondersteuning: Zorgvernieuwingsproject zorgverzekeraars

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Success and failure rates of the consecutive neutral density filters;
2. (Δ) SEQ values. Differences will be considered statistical significant if p<0.05.

A differences of 5% success rate (1) and >0.2 diopters Δ SEQ (1 and 2) will be considered clinical significant.

Toelichting onderzoek

Achtergrond van het onderzoek

The software of the PlustoptiX devices is developed for pupils up to 7.8 to 8mm in size. In the study “a double blind randomized study on the efficacy of cyclopentolate 1% and tropicamide 1% in children (MEC nr NL32954.098 /1010-077; NTR 2476), pupil sizes will be over 8mm in a considerable amount of cases. To avoid drop-out neutral density filters are used to decrease light intensity. This study will investigate the validity of the use of neutral density. Further the optimal filter will be determined.

Doel van het onderzoek

The software of the PlustoptiX devices is developed for pupils up to 7.8 to 8mm in size. In the study “a double blind randomized study on the efficacy of cyclopentolate 1% and tropicamide 1% in children (MEC nr NL32954.098 /1010-077; NTR 2476), pupil sizes will be over 8mm in a considerable amount of cases. To avoid drop-out neutral density filters are used to decrease light intensity. This study will investigate the validity of the use of neutral density. Further the optimal filter will be determined.

Onderzoeksopzet

For both protocols: To prevent differences in pupil dynamics eligible subjects will be adapted to the room light for 5 minutes. During this time the purpose of the measurements will be explained, time investment (3 minutes) be discussed and oral consent asked. After consent measurements will be made. Success (data) or failure (no data) will be recorded. Pupil size, sfere, cylinder and axes of each measurement will be noted. Refractive outcomes will be converted in SEQ.

For the un-dilated protocol the measurements will be made in consecutive order; entry measurements without glasses, measurements with glasses, measurements with glasses and filter 91% etc.

For the dilated protocol the measurements will take place 35 minutes after application of the cycloplegics. The refractive state of the subject will be assessed with the Retinomax K-plus 3. The values found will be placed in a trial frame. Measurements will be made in consecutive

order; entry measurements without trail glasses, measurements with trial glasses, measurements with trail glasses and filter 91% etc.

Onderzoeksproduct en/of interventie

Measurements are made with the Powerrefractor II; software installed of the PlustoptiX A09. Both for the un- and dilated: A entry measurement with and without glasses will be made. Thereafter three measurements will be made with glasses and consecutive neutral density filters. Five different absorptive neutral density filters will be used; 91% (Newport Ltd), 79% (Newport Ltd), 62% (Thorlabs Ltd), 46% (Thorlabs Ltd) and 34% (Thorlabs Ltd).

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Un-dilated pupils:

Healthy volunteers, aged 35 to 60 years, having hypermetropia corrected with unifocal glasses, visiting the department Ophthalmology either as a patient or as an accompanying person.

Dilated pupils:

Healthy volunteers, aged 18 to 60, having hypermetropia, which received cycloplegics.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

For both un-dilated and dilated subjects:

Cataract and/or vitreous bleeding, and/or abnormal shaped pupils or no oral consent.

For un-dilated subjects pupil sizes < 3.5 mm or > 7.8mm.

For dilated subjects pupil sizes <6mm.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-09-2010
Aantal proefpersonen:	41
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2639
NTR-old	NTR2767
Ander register	METC Medisch Centrum Haaglanden : METC 10-120
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A