Can early glasses prevent the development of amblyopia in children with high refractive errors at age one?

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To investigate whether treating children with high refractive errors at age one with glasses prevents the development of amblyopia.

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

Summary

ID

NL-OMON51136

Source
ToetsingOnline

Brief title
The Early Glasses Study (EGS)

Condition

- Vision disorders

Synonym
amblyopia, lazy eye

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: collectebusfonds (Stichting Lijf en Leven),De bril is gratis voor ouders en kind. In principe worden de kosten van brillen uit het subsidiegeld betaald. Wij hebben echter bij het Carl Zeiss Förderfonds extra ondersteuning aangevraagd

voor ondersteuning van de brillenglazen. Deze stichting was enthousiast over ons wetenschappelijk onderzoek en heeft besloten om de studie in natura te ondersteunen door de kinderbrillenglazen gratis ter beschikking te stellen, mits deze wel verstrekt worden middels door Zeiss gecontracteerde opticiens. Deze schenking is zonder verdere condities. De in Amsterdam gevestigde Nederlandse leverancier en fabrikant van kinderbrilmonturen, Vingino, More B.V, heeft zich bereid verklaard om met korting een selectie van circa 30 typen kinderbrilmonturen te leveren. In de praktijk komt het erop neer dat we voor de meeste monturen uit dit aanbod (het zijn voornamelijk overjarige modellen) 10 euro en in enkele gevallen 30 euro per stuk zullen betalen. Aan deze levering met korting zijn verder geen condities verbonden. De orthoptische meetinstrumenten worden door 3 bedrijven met korting geleverd: Medical Workshop b.v., HEINE Optotechnik GmbH & Co en OCULUS Optikgeräte GmbH. Ook aan deze korting zijn verder geen condities verbonden. Zowel Zeiss, Vingino, Medical Workshop b.v., HEINE Optotechnik GmbH & Co en OCULUS Optikgeräte GmbH staan als bijdragende sponsors op de website vermeld. De controle van de kwaliteit van de kinderbrillen, zowel van de kinderbrilmonturen als de kinderbrilglazen, wordt gedaan door onafhankelijk opticien, Douwe Bakker, in dienst van de studie.

Intervention

Keyword: amblyopia, glasses, refractive error, vision screening

Outcome measures

Primary outcome

The occurrence of amblyopia at the final examination, stratified according to

visual acuity of the amblyopic eye in the intervention group and in the control

group. The final examination will take place at the age of 4, unless children

have been referred to an orthoptist and/or ophthalmologist before, for example

when amblyopia or strabismus are suspected before the age of 4.

Secondary outcome

Secondary outcome measures are:

- Prevalence of amblyopia at age 1;

- Type and severity of refractive error at age 1;

- Occurrence of amblyopia at the final examination, stratified according to

visual acuity of the amblyopic eye in the children without high refractive

error at age 1;

- Pre-literacy skills in the intervention and control group at age 4;

- Occurrence of strabismus, determined at the final examination in all groups.

Other outcome measures:

- Electronically measured compliance with spectacles wearing;

- The evolution of refractive error between age 1 and 4;

- Gender;

- Family history for ocular disease;

- Ethnicity;

- Parental level of education, social economic status and language skill.

Study description

Background summary

Amblyopia (prevalence approx. 3.4%) develops in early childhood when the child*s eyes have severe refractive error, when they squint, or both. It can effectively be treated with glasses and patching the better eye, but treatment should start before age 6 to be effective. Therefore, visual acuity should be measured in all children aged 4-5 to detect amblyopia early enough. In an effort to prevent the development of amblyopia all together, in some countries devices are being used to measure refractive error in toddlers and, when refractive error is severe, fit them glasses before amblyopia develops. In Flanders, the measurement of refractive error in 1- and 2.5-year-olds began in 2012, in addition to regular vision screening with measurement of the visual acuity at the age of 3, 4 and 5. Between 2012 and 2017 the percentage of 4-year-old glasses wearing children had risen from 4.7% to 6.4%, but it was unknown how many cases of amblyopia had been prevented from developing. A prospective comparison seems warranted between this new method and the current national vision screening program in the Netherlands.

Study objective

To investigate whether treating children with high refractive errors at age one with glasses prevents the development of amblyopia.

Study design

We will perform an interventional prevention study comparing the effect of prescribing glasses to children with high refractive error at age 1 (intervention) versus no prescription of glasses (control) on the prevalence of amblyopia at age 4. One-year-old children will be recruited by the study physician after visiting the children*s healthcare centres (CHCs, *consultatiebureaus*) at 11 or 14 months. Refractive error will be determined by retinoscopy in cycloplegia in all children. Children with refractive error exceeding the AAPOS 2003 criteria are considered to have high refractive error in this study. We anticipate that 8% of all children will have high refractive error according to these criteria. These children will be randomized to the intervention group or the control group, and will be followed up until final visual acuity is measured at age 4. In case amblyopia or strabismus develops during the course of the study, children will be referred for immediate treatment, and visual acuity at the moment of referral will be used as final measurement. In all children in the intervention group compliance with wearing spectacles will be measured electronically. At age 4 pre-literacy skills will be measured in the intervention group and the control group.
The majority of children, approximately 92%, will have mild or no refractive error. After the first examination, these children will continue regular screening at the CHCs. They will have their visual acuity measured at the age of 4 as part of standard vision screening in the Netherlands at the CHCs. These data will be obtained from the CHCs. If there is uncertainty about the visual outcome at the CHC, the child will receive a supplementary evaluation. Children with amblyopia or strabismus at the age of one will be excluded from this study and referred for immediate treatment. Due to ethical considerations, children with severe refractive error at the age of one, i.e. exceeding the AAPOS 2003 criteria twofold, will also be excluded from this study and referred for immediate treatment with glasses. Due the nature and design of the study, blinding of the researchers on site and of participants will not be possible.

Intervention

Children assigned to the intervention group will be examined by the study orthoptist one to three times yearly until final examination, and will be fitted with glasses, based on accurate determinations of refractive error by retinoscopy in cycloplegia. Children with high refractive error assigned to the control group will be examined by the study orthoptist one to three times yearly until final examination, but will not be fitted with glasses.

Study burden and risks

The expected burden and risks associated with participation can be considered minimal. For children who have mild or no refractive error, the investigation will be limited to the first examination at the age of 1. Children with high refractive error are followed up 1, 2 or 3 times a year, as decided upon by the study orthoptist, leading up to a total of additional 3-9 additional visits until the age of 4. Each visit will take 45-60 minutes. In order to measure refractive error accurately, retinoscopy will be done by study orthoptists after the instillation of cycloplegic eye drops, as happens daily in clinical practice of orthoptists and pediatric ophthalmologists. We will install 1 eyedrop of cyclopentolate 1% in each eye, which we will repeat after 10 minutes. Cyclopentolate can cause sleepiness in rare cases: children are difficult to awaken for several minutes, but can be awoken thereafter, which is without sequelae without exception. There are no risks associated with the prescription of glasses at the age of one. All children will be examined at age one by highly skilled orthoptists, who can detect amblyopia and other eye disorders immediately and will be able to report to the parents about the health of their children*s eyes in detail. A certain gain for both the intervention and the control group is that the eyes of the children are examined annually or up to three times a year by highly skilled orthoptists so that any beginning of amblyopia or another eye disorder is timely detected. Possible gain for participants in the intervention group includes the prevention of amblyopia and/or a positive effect on preschool reading skills.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

All children of 12-18 months old, born after uneventful pregnancy (>36 weeks), registered at one of the participating children*s healthcare centers (CHCs) and with informed consent by the parents/guardians

Exclusion criteria

Prematurity and perinatal birth damage; Congenital syndromes; Psychomotor retardation; Known hereditary defects; Known cardiac disease; Severe comorbidity; Children*s whose parents do not agree to cyclopegia with the use of cyclopentolate 1% eye drops, Refractive error higher than the AAPOS 2003 criteria twofold, Strabismus; Amblyopia; Ptosis; Cataract or other media opacity; Other ophthalmic disease requiring immediate referral.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-05-2021
Enrollment:	2000
Type:	Actual

Medical products/devices used

Generic name:	The prescription of Glasses / Spectacles from age 1 onwards
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	30-04-2021
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT04740593
CCMO	NL76412.078.21