Screening for problems in eyes of children study (SPECS)

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Ethical review	Approved WMO
Status	Pending
Health condition type	Eye disorders congenital
Study type	Observational non invasive

Summary

ID

NL-OMON31132

Source
ToetsingOnline

Brief title
Screening for eye problems in children (SPECS)

Condition

- Eye disorders congenital
- Congenital eye disorders (excl glaucoma)

Synonym
refraction anomalies = need for spectacles

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Cordial Medical stelt apparaat ter beschikking voor onderzoek

Intervention

Keyword: Child, Eyes, Screening

Outcome measures

Primary outcome

A) Outcome of standard investigation and outcome of each screening method.

B) Time needed for standard investigation and each screening method.

Secondary outcome

1. What is the outcome of the standard investigation by a trained orthoptist?

2. What is the outcome of screening with real time videoretinoscopy using the Plusoptix [S04] screener, without and with mydriasis?

3. What is the outcome of screening using a handheld autorefractometer screener (Retinomax®), without and with mydriasis?

4. How does the Plusoptix ®) compare with the outcome of the gold standard of investigation by a trained orthoptist?

5. How does the Retinomax® compare with the outcome of the gold standard of investigation by a trained orthoptist?

6. How does the Plusoptix compare with the outcome of the Retinomax®?

7. What are the limitations associated with use of the Plusoptix ® and Retinomax ® (e.g. strabismus, nystagmus, lack of co-operation)?

8. How much time is needed for retinoscopy by a trained orthoptist?

9. How much time is needed for screening using Plusoptix®)

10. How much time is needed for screening using Retinomax®?

Study description

Background summary

Eye problems which threaten vision (including amblyopia, strabismus and significant refractive errors) are estimated to occur in 2% - 5% of pre-school children (1). Earlier identification of visual abnormalities is intended to lead to earlier treatment and a better long-term visual outcome (2).
In the Netherlands visual function is tested 8 times between birth and the ages of 8 years 3. This screening is performed at the Well Baby Clinics or during visits by the school doctor. Screening of children with developmental problems is not carried out systematically.
The present methods for screening eye function in children are time consuming. Therefore a reliable and rapid screening method could be of great benefit (4). Two new screening methods have recently become available. These are a) the method using computerized videoretinoscopy (Plusoptix ®) and b) the method using a handheld refractometer (Retinomax®).
Before a screening method is considered for large scale screening in the Netherlands it must be evaluated and validated. A study using the Plusoptix ® method has recently been carried out in Flanders in Belgium and has shown promising results (5). A study using the Retinomax® has been carried out in Brussels (6). The screening tests are not uncomfortable, painful, invasive nor time consuming. No eye drops, waiting or other special preparation is necessary.

Study objective

The aim of this study is to compare the results of 2 methods for screening of eye function in children with the standard investigation by the orthoptist. The outcome of the tests and the time involved will be compared.

Two screening methods will be studied.

I Computerized videoretinoscopy (Plusoptix ®) is a relatively new method for screening of eye function and is suitable for use in young children and in people with developmental problems as co-operation is not required. Dilation of the pupils is not necessary. Binocular measurement of both eyes together is possible within a few seconds.

II The handheld autorefractometer (Retinomax®). This is a monocular autorefractor using a fogging technique which aims to minimize accommodation. Dilation of the pupils is not necessary. Measurements are repeated and the complete screening takes about half a minute per eye.

Study design

This is a prospective study. The cohort consists of all children fulfilling the inclusion criteria during the period of the study.
Both the user of the screening methods (using the Plusoptix® and Retinomax®) and the orthoptist using the standard method will be *masked* as to the child*s outcome using the other method.
The student will screen children using the Plusoptix® and the Retinomax®.
The orthoptist will perform the standard investigation.
The results of screening using Plusoptix® and Retinomax® of each child will be recorded, as well as the results of the standard examination (retinoscopy after instillation of cycloplegic eye drops and autorefraction when possible) by the orthoptist. Screening using the Plusoptix® and Retinomax® will be repeated after instillation of cycloplegic eye drops. Furthermore eye alignment, presence of nystagmus and, if applicable, the angle of strabismus will be noted.
The results of the screening tests and standard investigation will be kept separately and the student and orthoptist will not be able to see each other*s results. The time needed per test will be noted as well as the co-operation of the child. The outcome of each method will be noted. The possibility to detect strabismus with the Plusoptix® and Retinomax® will be evaluated
The results of the standard investigation and the screening methods will be compared after every 50 children who have been included and at the end of the study period.

Parents of children attending the Department of Paediatric Ophthalmology of the Leiden University Medical Centre will be invited to let their children participate in this study. They will be given spoken and written information about the tests and if they agree a written consent form will be signed.

Study burden and risks

There are no risks involved in the use of the screening methods. They do not cause pain or discomfort.
The time involved for parents is approximately 10 minutes extra on top of the time for the regular investigation.
Participation in this study has no advantages for the individual child at present. It is hoped that these and other children will be able to be screened more quickly and easily if these methods are introduced in the future.

If this study shows that the Plusoptix® and/or Retinomax® give results comparable to those of the investigation by the orthoptist it may provide data which will influence the form in which the eye screening of young children is carried out by ophthalmologists and orthoptists as well as at the Well Baby clinics and school doctor*s visit the Netherlands. These methods may also be useful for screening children who are difficult to investigate (with psychomotor developmental delay or other problems). The findings may later contribute to changes in international screening programmes.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

All children referred to the Department of Paediatric Ophthalmology of the Leiden University Medical Centre between 01-09-2007 and 31-12-2007 will be included, when the parents give written consent.

Exclusion criteria

When parents do not consent
When the child does not co-operate

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2007
Enrollment:	200
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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
CCMO	NL17862.058.07