

Study on two new methods for testing visual field in children with brain disease

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To compare different methods for visual field testing in young and/or neurologically impaired children, to determine which test is most useful in detecting visual field defects.

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

Summary

ID

NL-OMON55046

Source

ToetsingOnline

Brief title

PP_OCT_CVI

Condition

- Eye disorders congenital
- Vision disorders
- Nervous system neoplasms benign

Synonym

Cerebral Visual Impairment, Cortical Visual Impairment

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Dr. F.P. Fischer Stichting;stichting ODAS;Rotterdamse Stichting Blindenbelangen;Janivo. (De eerste 3 stichtingen via UitZicht)

Intervention

Keyword: Cerebral Visual Impairment (CVI), OCT, Pupil Perimetry, Visual Field Tests

Outcome measures

Primary outcome

Sensitivity, specificity, reliability of measurement and test-retest

reliability of Standard Conventional Perimetry, Pupil Perimetry and OCT for

detecting visual field defects

Secondary outcome

To provide evidence for possible mechanisms of reorganizational recovery of the

visual system or signs of adaptive neuronal plasticity in the child suffering

from Cerebral Visual Impairment.

Study description

Background summary

Children affected by a Cerebral Visual Impairment often suffer from a visual field defect which may interfere with learning, reading, and rehabilitation therapies.

However, there are very few methods for testing visual field in young and/or neurologically impaired children. Furthermore, scientific studies that compare the usability of different visual field testing methods in this patient group are lacking.

Hence, there is little understanding of which methods should be used to examine visual field defects in these children.

Study objective

To compare different methods for visual field testing in young and/or neurologically impaired children, to determine which test is most useful in detecting visual field defects.

Study design

Prospective observational cohort study.

Study burden and risks

Participants will need to be tested with all the subjective and objective methods for visual field testing thrice mostly during their standard control visits. All tests are non-invasive, most are part of the standard ophthalmologic assessment and take 10-20 minutes to complete. As such, there are no potential risks for participating in this study.

This study is designed to include children, because the difficulties in testing visual field in young and/or neurologically impaired children do not apply to adult patients. Therefore, it can only be done using this patient group.

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

- Children, 5-18 years old, affected by CVI with a diagnosed VFD and able to perform Standard Conventional Perimetry
- Visual acuity of at least 10% or corrected to normal
- Capable of successfully performing a standard perimetry test
- Informed and having given informed consent (either by patient and/or parents/legal guardian)

Exclusion criteria

- Epilepsy prior to surgery or still active
- Any other ocular or neurological disorders, previous neurological or ophthalmologic surgery not associated with this study indication

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-02-2020

Enrollment: 40

Type: Anticipated

Ethics review

Approved WMO

Date: 01-04-2021

Application type: First submission

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	NL72502.041.19