

WHEN MAY VARIATION IN DEVIATIONS OF STRABISMUS BE CONSIDERED AS REAL CHANGE?

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To investigate inter-examiner variability of the alternate prism and cover test (APCT) measurements of ocular deviation at near and distance fixation, and to compare variability between adults/teenagers and children.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Ocular neuromuscular disorders
Study type	Observational non invasive

Summary

ID

NL-OMON35612

Source

ToetsingOnline

Brief title

Variability of the APCT

Condition

- Ocular neuromuscular disorders

Synonym

squinting, strabismus

Research involving

Human

Sponsors and support

Primary sponsor: Oogziekenhuis Rotterdam

Source(s) of monetary or material Support: Dit onderzoek geschiedt budgetneutraal in het kader van stage orthoptie.

Intervention

Keyword: Alternate prism and cover test, Strabismus, Variability between orthoptists

Outcome measures

Primary outcome

Inter-examiner difference in ocular deviation at near and distance fixation.

Limits of agreement at 95% level (i.e. mean difference $\pm 1.96 \times \text{SD}$).

Secondary outcome

n.v.t.

Study description

Background summary

A guiding value can be helpful for clinicians to determine whether measured differences in strabismus deviation are likely to represent a true change.

Study objective

To investigate inter-examiner variability of the alternate prism and cover test (APCT) measurements of ocular deviation at near and distance fixation, and to compare variability between adults/teenagers and children.

Study design

Cross-sectional prospective study.

Study burden and risks

Risks are negligible; burden is low. Study-related extra time required is 30 minutes (i.e. 3X5 minutes for actual measurements plus waiting time). Children (< 12 yrs) will be included because variability is anticipated to be larger.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)

Adolescents (16-17 years)

Adults (18-64 years)

Children (2-11 years)

Elderly (65 years and older)

Inclusion criteria

Adults and teenagers (≥ 12).

Children (< 12) allowing prism bar in front of their eyes.

Isolated strabismic horizontal deviations or combined horizontal and vertical deviations.

Patients are wearing full refractive correction.

At least one eye is able to reach and fixate in primary position.

Visual acuity of at least 20/200 in either eye with full refractive correction.

Capable of fixation movement and keeping fixation when dominant fixing eye is covered.

Exclusion criteria

Eccentric fixation

Children who did not have cycloplegic refraction in previous 6 months.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	20-03-2012
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO	
Date:	22-12-2011
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
CCMO	NL38425.078.11