Efficacy of occlusion therapy initiated in patients with untreated amblyopia beyond 7 years of age

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

Summary

ID

NL-OMON31331

Source
ToetsingOnline

Brief title
Efficacy of occlusion therapy

Condition

- Vision disorders

Synonym
Amblyopia, lazy eye

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Haaglanden, locatie Westeinde
Source(s) of monetary or material Support: Onderzoek wordt niet gefinancierd

Intervention

Keyword: Amblyopia, efficacy, occlusion therapy, visual acuity

Outcome measures

Primary outcome

Primary outcome parameter is visual acuity of the amblyopic eye five weeks after cessation of occlusion therapy.

Secondary outcome

Secondary outcome parameters are cause of amblyopia, age at start occlusion therapy, fixation, visual acuity of the amblyopic eye at start and end of occlusion therapy, anisometropia, and aniseikonia.

Study description

Background summary

In about a third of patients, amblyopia persists in adulthood and thereby increasing the risk of bilateral visual impairment due to loss of vision in the nonamblyopic eye.
Amblyopia is commonly treated before age of six, but there is no agreement up to which age amblyopia can be successful treated. Observations of improvement in vision of the amblyopic eye following the loss of the good eye suggests that upper age limit for response to amblyopia therapy may not be as rigid as previously understood. The efficacy of occlusion therapy, thus, whether visual improvement after occlusion therapy in older amblyopes remains or decreases after occlusion is discontinued, is insufficiently investigated prospectively.

Study objective

The primary purpose of this study is to assess the efficacy of occlusion therapy (visual acuity of the amblyopic eye five weeks after cessation of occlusion therapy) in previously untreated patient with amblyopia between seven and forty years of age. The secondary purposes are to determine factors, which influence the stability of the response (visual acuity of the amblyopic eye five weeks after cessation of occlusion therapy).

Study design

The study is designed as a prospective randomised crossover investigator-initiated trial.

Intervention

Patients receive occlusion therapy (intervention) of the sound eye, three hours per day/ seven days a week for 5 weeks and are instructed to perform near visual activities while patching.

Study burden and risks

The risks involved in the study are identical to those that would be present for a patient treated with the study treatment regimens who is not participating in the study and pose no additional known risks. Skin irritation due to patching or diplopia is unlikely in view of the small number of hours of daily patching prescribed.

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

All patients between seven and forty years of age, diagnosed with amblyopia associated with strabismus and/ or anisometropia (anisometropia <= >1.0 D of spherical equivalent or >1.50 D difference in astigmatism in any meridian) will be eligible for the study.

Exclusion criteria

Previous treatment for amblyopia (includes occlusion, or pharmacological defocusing), previous optical correction of the amblyopic eye, ocular cause for reduced visual acuity, diminished acuity due to medication, brain damage, or trauma, neurological disorders, and eye muscle palsies.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-11-2007
Enrollment:	22

Type:	Actual

Ethics review

Approved WMO Date:	31-10-2007
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL18438.098.07