Clinical and psychosocial determinants influencing treatment effect of occlusion therapy and rate of recurrence in previously untreated patients with amblyopia between 12 and 40 years of age

Published: 06-07-2011
Last updated: 27-04-2024

The primary purpose is the efficacy of occlusion therapy initiated in patients with untreated amblyopia between twelve and forty years of age. The secondary purposes are rate of recurrence, refractive adaptation, and the social-economic and ethic...

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

Summary

ID

NL-OMON35897

Source
ToetsingOnline

Brief title
Efficacy of occlusion therapy (EOT2)

Condition

- Vision disorders

Synonym
Amblyopia, lazy eye

Research involving

Human

Sponsors and support

Primary sponsor: Medisch Centrum Haaglanden
Source(s) of monetary or material Support: Wetenschapsfonds Medisch Centrum Haaglanden

Intervention

Keyword: Amblyopia, efficacy, occlusion therapy, visual acuity

Outcome measures

Primary outcome

Primary outcome parameter:

1) Improvement of visual acuity in logMAR, from best-corrected visual acuity

(after refractive adaptation) of the amblyopic eye at start occlusion therapy

to visual acuity at the end of occlusion therapy (maximal treatment effect).

2) Response rate of treatment of the amblyopic eye, improvement of at least two

lines from start to end of occlusion therapy.

Secondary outcome

1) Rate of recurrence: Measurement of visual acuity in logMAR of the amblyopic

eye nine months after cessation of treatment at least two lines worse than

visual acuity at end of occlusion therapy

2) Refractive adaptation: Visual acuity in logMAR, uncorrected visual acuity of

the amblyopic eye to 18 weeks after prescription of optical correction, as a

function of age, type of amblyopia, and refractive error.

3) By means of questionnaires: Evaluation and influence of the social-economic

and ethic status and the psychosocial factors on compliance to occlusion

therapy.

Study description

Background summary

Amblyopia, defined as loss of visual function, caused by strabismus, anisometropia, and/or visual deprivation in the absence of ocular pathology, is commonly treated by occlusion therapy before age of six, limiting by the end of the sensitive period. However, recent studies suggest that the plasticity of the visual system extends into adolescents. In about a third of patients, 1% of the population, amblyopia persists in adulthood and thereby increasing the risk of bilateral visual impairment due to loss of vision in the nonamblyopic eye. This leads to decrease in quality of life and to increase costs to the healthcare system. The efficacy of occlusion therapy in adult patients, thus, whether visual improvement after treatment remains or decreases after occlusion is discontinued, is insufficiently investigated prospectively. Whether psychological factors or decreasing plasticity limits treatment effect in amblyopic adults is not clear.

Study objective

The primary purpose is the efficacy of occlusion therapy initiated in patients with untreated amblyopia between twelve and forty years of age.

The secondary purposes are rate of recurrence, refractive adaptation, and the social-economic and ethic status and the psychosocial factors as predictor for compliance to occlusion therapy.

Study design

This study is designed as a prospective interventional study.
The recruitment of patients is expected to start in June 2011 and will last until March 2012. The follow up controls take place until November 2013.
Each participants is prescribed optical correction (if needed). Participants are seen at 6 weeks intervals up to 18 weeks (end of period of refractive adaptation).
After refractive adaptation, each participant will receive part-time occlusion (3 hours a day) on the sound eye until there is no further improvement (less than one logMAR line) of visual acuity of the amblyopic eye, for a period of maximal 18 weeks. Participants are tested within 6 weeks intervals (for a period of maximal 4 months).
Follow up visits take place three, six and nine months after discontinuation of treatment.

Participants are asked to fulfil a questionnaire for the evaluation of the social-economic and ethic status at the day of inclusion, and a questionnaire about the psychosocial determinants during occlusion therapy is given six weeks after start of occlusion therapy.

Intervention

All participants were prescribed three hours per day of part-time occlusion on the sound eye for a period of maximal 4 months.

Study burden and risks

Part-time occlusion is the standard therapy for amblyopia treatment. Skin irritation due to patching or persistent diplopia is unlikely in view of the small number of hours of daily patching prescribed.

Contacts

Public
Medisch Centrum Haaglanden, locatie Westeinde

Lijnbaan 32
Den Haag 2512VA
NL
Scientific
Medisch Centrum Haaglanden, locatie Westeinde

Lijnbaan 32
Den Haag 2512VA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Inclusion criteria

-Patients between twelve and forty years of age, diagnosed with untreated amblyopia associated with strabismus and/ or anisometropia
-Visual acuity in the amblyopic eye at least 1.0 logMAR (logarithm of the minimum angle of resolution) using best correction based on the results of a cycloplegic refraction

Exclusion criteria

Previous treatment for amblyopia (occlusion therapy, atropinisation, penalisation), reduced visual acuity due to ocular cause or medication, brain damage, or trauma, neurological disorders, and eye muscle palsies.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2011
Enrollment:	36
Type:	Actual

Ethics review

Approved WMO

Date:	06-07-2011
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

	metc-ldd@lumc.nl
Approved WMO Date:	02-09-2013
Application type:	Amendment
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	NL35519.098.11
Other	TC = 2711