Invloed van klinische en sociaal-psychologische factoren op het effect van de afplakbehandeling bij patiënten met een niet behandeld lui oog tussen 12 en 40 jaar.

Gepubliceerd: 24-01-2011 Laatst bijgewerkt: 18-08-2022

Efficacy of occlusion therapy initiated in patients with untreated amblyopia between twelve and forty years of age is effective.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26407

Bron
NTR

Verkorte titel
OT2

Aandoening

Rationale:
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.

Trefwoorden:
Amblyopie, effektiviteit, afplakbehandeling, visus
Amblyopia, efficacy, occlusion therapy, visual acuity

Ondersteuning

Primaire sponsor: Medisch Centrum Haaglanden Den Haag, locatie Westeinde
Overige ondersteuning: Aanvraag bij fonds ingedient, uitslag nog niet bekennt

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Improvement of visual acuity in LogMAR, from best-corrected visual acuity (after refractive adaptation) of the amblyopic eye at start to 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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

Efficacy of occlusion therapy initiated in patients with untreated amblyopia between twelve and forty years of age is effective.

Onderzoeksopzet

After the enrolment, each patient is prescribed optical correction (if needed). Patients are seen at 6 weeks intervals (within a time window of ±1 week) up to 18 weeks (end of period of refractive adaptation).
After refractive adaptation, each patient will receive part-time occlusion 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. Patients are tested within 6 weeks intervals.
To determine the rate of recurrence following successful treatment (improvement of visual acuity at least two LogMAR lines from start to end of occlusion therapy) after treatment is discontinued, patients are continued in an observation phase for nine months. Follow-up visits take place three, six and nine months after discontinuation of treatment.

Onderzoeksproduct en/of interventie

All patients are prescribed three hours per day of part-time occlusion on the sound eye for a period of maximal 18 weeks.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. All patients between twelve and forty years of age, diagnosed with amblyopia associated with strabismus and/ or anisometropia (>1.0 D of spherical equivalent or >1.50 D difference in astigmatism in any meridian);

2. Visual acuity in the amblyopic eye at least 1.3 LogMAR, using best correction based on the results of a cycloplegic refraction performed within past two months.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Previous treatment for amblyopia (includes occlusion, or pharmacological defocusing);

2. Ocular cause for reduced visual acuity;

3. Diminished acuity due to medication;

4. Brain damage, or trauma, neurological disorders, and eye muscle palsies;

5. Best corrected visual acuity in the amblyopic eye less than 1.3 LogMAR.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Factorieel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-05-2011

Aantal proefpersonen:	44
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	24-01-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2586
NTR-old	NTR2711
Ander register	ABR : 35519
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

Pediatric Eye Disease Investigator Group (2005) Randomized trial of treatment of amblyopia in children aged 7 to 17 years. Arch Ophthalmol, 123, 437-47.
Loudon, SE., Passchier, J., Chaker, L., de Vos, S., Fronius, M., Harrad, RA., Looman, CW., Simonsz, B., Simonsz, HJ. (2009) Psychological causes of non-compliance with electronically monitored occlusion therapy for amblyopia. Br J Ophthalmol, 93(11), 1499-503.
Fronius, M., Bachert, I., Lüchtenberg, M. (2009) Electronic monitoring of occlusion treatment

for amblyopia in patients aged 7 to 16 years. Graefes Arch Clin Exp Ophthalmol, 1401-8.