MD-clip trial

Gepubliceerd: 11-11-2016 Laatst bijgewerkt: 18-08-2022

- The enhanced prism spectacle (MD-clip) will increase the Quality of Life in patients with severe macula degeneration - The MD-clip will increase vision in patients with severe macula degeneration

Ethische beoordeling	Niet van toepassing
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27967

Bron
NTR

Verkorte titel
MD-clip

Aandoening

Patients experiencing severe irreversible vision loss as a result of age-related macular degeneration (ARMD)

Ondersteuning

Primaire sponsor: Erasmus Medical Center
Overige ondersteuning: An unrestricted research grant was provide by Revoir Group, Ergra low vision

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome was quality of life as measured with the subscale distance activities and the composite scale of the NEI-VFQ-25

Toelichting onderzoek

Achtergrond van het onderzoek

On the long term most patients with age-related macular degeneration (ARMD) will experience severe irreversible vision loss. These low vision patients might benefit from an enhanced spectacle (MD-clip), equipped with several features, such as a prism using the outside of the macula. Experience in daily practice has shown that the MD-clip improves visual functioning. To substantiate these findings, we have undertaken this study to investigate the effect of the MD-clip on quality of life (QOL), particularly when the vision is actually improved. Additionally, we study the vision enhanced by the MD-clip, as well as the burden caused by the disease. In this prospective, open-label, randomized controlled trial, patients were randomized assigned (1:1) to either the MD-clip group or the waiting list.

Doel van het onderzoek

- The enhanced prism spectacle (MD-clip) will increase the Quality of Life in patients with severe macula degeneration
- The MD-clip will increase vision in patients with severe macula degeneration

Onderzoeksopzet

baseline, and six weeks after initial visit.

Onderzoeksproduct en/of interventie

The experimental groups wears the MD-clip 3 weeks, the control group receive the MD-Clip after the study

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- diagnosis of age-related macular degeneration (AMD)

- aged at least 18 years

- signed informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- insufficient capacities of the Dutch language

- handicaps impeding participation

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd

Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-09-2014
Aantal proefpersonen:	160
Type:	Werkelijke startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL5944
NTR-old	NTR6126
Ander register	Ergra Low Vision : OVI141516

Resultaten

Samenvatting resultaten

Visser MS, Dieleman M, Klijn S, Timman R, Lundström M, Busschbach JJV & Reus NJ. Validation, test-retest reliability and norm scores for the Dutch Catquest-9SF. Acta Ophthalm. 2016;Oct 24. doi: 10.1111/aos.13287.