

# MD-clip trial

No registrations found.

|                              |                     |
|------------------------------|---------------------|
| <b>Ethical review</b>        | Not applicable      |
| <b>Status</b>                | Recruitment stopped |
| <b>Health condition type</b> | -                   |
| <b>Study type</b>            | Interventional      |

## Summary

### ID

NL-OMON27967

### Source

NTR

### Brief title

MD-clip

### Health condition

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

## Sponsors and support

**Primary sponsor:** Erasmus Medical Center

**Source(s) of monetary or material Support:** An unrestricted research grant was provided by Revoir Group, Ergra low vision

## Intervention

## Outcome measures

### Primary outcome

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

### Secondary outcome

Secondary outcomes were visual acuity (ETDRS) and contrast sensitivity (Pelli-Robson) measures with or with the MD-clip. Burden was measured using the EQ-5D-5L

## Study description

### Background summary

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.

### Study objective

- 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

### Study design

baseline, and six weeks after initial visit.

### Intervention

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

## Contacts

### Public

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## Eligibility criteria

### Inclusion criteria

- diagnosis of age-related macular degeneration (AMD)
- aged at least 18 years
- signed informed consent.

### Exclusion criteria

- insufficient capacities of the Dutch language
- handicaps impeding participation

## Study design

### Design

|                     |                             |
|---------------------|-----------------------------|
| Study type:         | Interventional              |
| Intervention model: | Parallel                    |
| Allocation:         | Randomized controlled trial |
| Masking:            | Open (masking not used)     |

Control: N/A , unknown

## Recruitment

NL  
Recruitment status: Recruitment stopped  
Start date (anticipated): 01-09-2014  
Enrollment: 160  
Type: Actual

## Ethics review

Not applicable  
Application type: Not applicable

## 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                           |
|----------|------------------------------|
| NTR-new  | NL5944                       |
| NTR-old  | NTR6126                      |
| Other    | Ergra Low Vision : OVI141516 |

## Study results

### Summary results

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 Ophthalmol.* 2016;Oct 24. doi: 10.1111/aos.13287.