# The retinal nerve fibre layer in patients with multiple sclerosis

Published: 28-12-2006
Last updated: 20-05-2024

In this study we would like to investigate whether the diameter of the retinal nerve fibre layer differs between healthy control persons and patients with different disease courses of MS.

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| **Ethical review** | Approved WMO |
| **Status** | Pending |
| **Health condition type** | Demyelinating disorders |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON30379

**Source**
ToetsingOnline

**Brief title**
Retinal nerve fibre layer in MS

### Condition

- Demyelinating disorders

**Synonym**
multiple sclerosis

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Groningen
**Source(s) of monetary or material Support:** Ministerie van OC&W

### Intervention

**Keyword:** Multiple sclerosis, Progression, Retinal nerve fibre layer

## Outcome measures

### Primary outcome

- The difference in diameter of the retinal nerve fibre layer between the

groups BMS, SPMS, PPMS and healthy control persons.

### Secondary outcome

- The correlation of clinical measures of disability and diameter of the

retinal nerve fibre layer.

- The correlation of MSSS scores and diameter of the retinal nerve fibre layer.

# Study description

### Background summary

There are two main disease courses in Multiple Sclerosis (MS): (1) a relapsing-remitting subtype (relapsing-remitting MS, RRMS) and (2) a chronic progressive disease course. In most patients, the disease begins with a relapsing-remitting course, which later converts to chronic progression (secondary progressive MS, SPMS). A small group of MS patients remains largely free of disease symptoms, even after very long disease duration. This disease course is called benign MS (BMS). The largest part of disability appears during the chronic progressive phase.

Recently, it has become clear, that tissue injury in MS is not only caused by inflammation but for a part also through neurodegeneration that is independent of inflammation. This degenerative process is called axonal degeneration. Axonal degeneration is the most important underlying mechanism of chronic progression in MS. The pathophysiology of axonal degeneration is unknown and there is thus no treatment for it.

There is no simple method to measure axonal degeneration in vivo. The diameter of the retinal nerve fibre layer can be measured with the ophthalmologic tool optical coherence tomography (OCT). As the retina is a part of the brain, we suspect that a decreased diameter of the retinal nerve fibre layer may be a measure of axonal degeneration in the brain. I an earlier study it was shown that the diametere of the retinal nerve fibre layer is significantly smaller in MS patients than in healthy control persons, but the different disease courses

of MS were not considered in this previous study.

### Study objective

In this study we would like to investigate whether the diameter of the retinal nerve fibre layer differs between healthy control persons and patients with different disease courses of MS.

### Study design

Explorative case control studie.

### Study burden and risks

Minimal risk and burden:
(1) one neurologic examination (to measure the extend of disability)
(2) one VEP examination (non-invasive)
(3) one OCT examination (non-invasive)

If the examination of the retina with OCT should not be possible without the use of pupil-dilating drugs, the patients will be treated once with pupil-dilating eye-drops (tropicamide 0.5%). This treatment carries the risk of an allergic reaction to tropicamide, the worsening of a narrow-angle-glaucoma, and the inability to drive a motor vehicle safely. We reduce the risk of an allergic reaction and glaucoma by excluding patients with allergy to tropicamide and know narrow-angle glaucoma. The cost of transport that becomes necessary after use of the pupil-dilating eye-drops will be paid for.

## Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

- age eightteen years or older
- written informed consent
- patients: diagnosis of multiple sclerosis, according to the McDonal criteria

## Exclusion criteria

- current or previous ophthalmologic disease other than optic neuritis
- contraindication for the use of mydriaticum: known allergy against tropicamide, known narrow-angle glaucoma.
- impaired visus as measured with visus examination cards (Snellen)

# Study design

## Design

**Study type:** Observational non invasive

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|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Diagnostic |

## Recruitment

NL

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|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-10-2006 |
| Enrollment: | 120 |
| Type: | Anticipated |

## Ethics review

Approved WMO
| | |
|---|---|
| Application type: | First submission |
| Review commission: | METC Universitair Medisch Centrum Groningen (Groningen) |

## 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 | NL14323.042.06 |