# Vitamin D treatment effect on retinal nerve fiber loss after optic neuritis

Published: 22-04-2010
Last updated: 19-03-2025

Primary objective:- To determine whether high dose vitamin D treatment in optic neuritis can reduce axonal loss as measured by OCT. Secondary objectives: - To investigate whether the occurrence of a second attack (defining clinically definite MS) is...

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Eye disorders NEC |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON34666

**Source**
ToetsingOnline

**Brief title**
VIDEO-trial

### Condition

- Eye disorders NEC
- Autoimmune disorders
- Demyelinating disorders

**Synonym**
inflammation of the optic nerve, Optic neuritis

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Erasmus MC, Universitair Medisch Centrum Rotterdam
**Source(s) of monetary or material Support:** Stichting MS Research

## Intervention

**Keyword:** Multiple sclerosis, Optic neuritis, Optical coherence tomography, Vitamin D

## Outcome measures

### Primary outcome

The main endpoint of this study is retinal nerve fiber layer thickness in ON patients with either vitamin D treatment of placebo, as measured by OCT.

### Secondary outcome

Secondary endpoints include effects of vitamin D on occurrence of second attack, visual outcome, clinical outcome and markers of immunology and neurodegeneration in blood and cerebrospinal fluid.

# Study description

### Background summary

There is accumulating evidence for a possible protective role of vitamin D in the development and disease course of multiple sclerosis (MS). Vitamin D is cheap, easy to administer, and safe. However, intervention studies are few. The first presenting symptom of MS is often optic neuritis (ON). Studies in MS and ON patients show a decrease in retinal nerve fiber layer (RNFL) thickness and macular volume, occurring within 1-3 months after ON. RNFL thickness can accurately be measured using optical coherence tomography (OCT): a novel and robust diagnostic tool. The rapid changes in RNFL after acute ON make it ideal for testing neuroprotective strategies over a short time frame. Other advantages of using ON patients to study the effect of vitamin D treatment include the possibility of starting early in the pathology, a relatively large availability of eligible patients because of the infrastructure and experience of our MS center, and a well-defined symptom-onset, making it a relatively homogenous group.

### Study objective

Primary objective:
- To determine whether high dose vitamin D treatment in optic neuritis can reduce axonal loss as measured by OCT.

Secondary objectives:
- To investigate whether the occurrence of a second attack (defining clinically definite MS) is postponed in the vitamin D treatment group compared to placebo;
- To investigate the effect of vitamin D treatment on visual outcome measures (visual acuity and visual field);
- To investigate the effect of vitamin D treatment on clinical outcome measures (EDSS, MSIS, fatigue scales);
- To investigate the effect of vitamin D treatment on immune and neurodegenerative markers in blood and CSF.

### Study design

Double-blind randomized placebo controlled trial

### Intervention

Patients with unilateral optic neuritis will be randomly assigned to receive either vitamin D (28.000 IU/week) or placebo. Follow-up will be 2 years.

### Study burden and risks

Participants will undergo clinical assessment at five standardized time points. Visual testing will be at four time points and OCT at three time points. Blood samples will be collected every three months for trial and safety purposes. CSF will be used for trial purposes; one extra spinal tap is required. Participants will be asked to fill out questionnaires at 4 time points. Vitamin D will be administered in a dosage of 28.000 IU/week, which is a safe dose according to the European consensus criteria.

## 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

- Single unilateral optic neuritis
- Age between 18 and 50 year
- Neuro-ophtalmological examination within 4 weeks of symptom onset

## Exclusion criteria

- Prior known optic neuritis, MS or prior symptoms suggestive of demyelination;
- Other suspected or established causes of vision loss (e.g. glaucoma, amblyopia);
- Inability to undergo OCT testing;
- Use of more than 1 vitamin supplement;
- Use of immunomodulatory therapy (e.g. interferone) in the 3 months prior to inclusion;
- Methylprednisolone treatment in the 3 months prior to inclusion;
- Renal failure (creatinine clearance of < 40 ml/min);
- Hypercalcemia;
- Sarcoidosis;
- Allergy to peanuts.

# Study design

## Design

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| Study phase: | 2 |
| Study type: | Interventional |

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| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Double blinded (masking used) |
| Control: | Placebo |
| Primary purpose: | Treatment |

### Recruitment

NL

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| Recruitment status: | Recruiting |
| Start date (anticipated): | 23-03-2011 |
| Enrollment: | 120 |
| Type: | Actual |

### Medical products/devices used

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| Product type: | Medicine |
| Brand name: | preparation by hospital pharmacy |
| Generic name: | Cholecalciferol |
| Registration: | Yes - NL outside intended use |

## Ethics review

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| Approved WMO Date: | 22-04-2010 |
| Application type: | First submission |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 01-07-2010 |
| Application type: | First submission |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 05-01-2011 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |

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| Approved WMO Date: | 18-01-2011 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |

# Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

ID: 26942
Source: NTR
Title:

## In other registers

| Register | ID |
|---|---|
| EudraCT | EUCTR2010-018498-39-NL |
| CCMO | NL31899.078.10 |
| OMON | NL-OMON26942 |