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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26942

Source
Nationaal Trial Register

Brief title
VIDEO-trial

Health condition

Multiple sclerosis, MS, vitamin D, optic neuritis, optical coherence tomography, OCT. Vitamine D, neuritis optica.

Sponsors and support

Primary sponsor: Erasmus Medical Center, Rotterdam
Source(s) of monetary or material Support: Dutch MS Research Foundation

Intervention

Outcome measures

Primary outcome

Retinal nerve fiber layer thickness, as measured by OCT at 6 months, 1 year and 2 years.

Secondary outcome

1. Time to second attack;

2. Visual acuity and visual field at 6 months, 1 year and 2 years;

3. Clinical outcome measures (EDSS, MSIS, FSS, HADS) at 6 months, 1 year and 2 years;

4. T2 lesion load on brain MRI at 2 years;

5. Markers of immunology and neurodegeneration and T cell function at 6 months, 1 year and 2 years.

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 scarce and increasingly difficult to perform.

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 useful 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. Finally, the well-defined symptom-onset makes it a relatively homogenous group.

We hypothesize that vitamin D treatment reduces axonal loss in ON patients primarily by its properties to modulate inflammation, and perhaps also by its neuroprotective properties.

The primary endpoint of this study is retinal nerve fiber layer thickness in ON patients with either vitamin D treatment or placebo, as measured by OCT. Other endpoints include effects of vitamin D on occurrence of second attack, visual outcome, clinical outcome and biomarkers in blood and cerebrospinal fluid.

We will conduct a double-blind randomized placebo controlled trial. Patients with unilateral

optic neuritis will be randomized to receive either vitamin D (14.000 IU/week) or placebo. Follow-up will be 2 years. OCT, collection of blood and cerebrospinal fluid, clinical assessment and visual testing will be performed at regular time points.

Vitamin D intervention studies are urgently needed. This protocol is innovative in using a novel, accurate diagnostic tool in a well-defined patient group.

Study objective

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 objective of this trial is to test the hypothesis that vitamin D treatment reduces axonal loss in ON patients, as measured by OCT.

Study design

1. OCT will be performed at baseline, 6 months, 1 year and 2 years;

2. Lumbar puncion and MRI will be performed at baseline and 2 years;

3. Clinical and visual testing will be performed at baseline, 6 months, 1 year and 2 years;

4. Blood samples will be collected every 3 months.

Intervention

Patients with unilateral optic neuritis will be randomly assigned to receive either vitamin D3 (Cholecalciferol) as an oral liquid medicine (14.000 IU/week) or placebo. Study medication will be administered once a week for 2 years.

Contacts

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Eligibility criteria

Inclusion criteria

1. Single unilateral ON;

2. Age between 18 and 50 year;

3. Neuro-ophtalmological examination within 4 weeks of symptom onset.

Exclusion criteria

1. Prior known ON, MS or prior symptoms suggestive of demyelination;

2. Other suspected or established causes of vision loss (e.g. glaucoma, amblyopia);

3. Inability to undergo OCT testing;

4. Use of more than 1 vitamin supplement;

5. Use of immunomodulatory therapy (e.g. interferone) in the 3 months prior to inclusion;

6. Methylprednisolone treatment in the 3 months prior to inclusion;

7. Allergy to peanuts.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2010
Enrollment:	120
Type:	Anticipated

Ethics review

Positive opinion

Date:	19-04-2010
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 34666
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL2177

Register	ID
NTR-old	NTR2301
CCMO	NL31899.078.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON34666

Study results

Summary results
N/A