Vitamin D status and the T cell compartment in Multiple Sclerosis

Published: 27-05-2008
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The purpose of this study is to investigate the association between T cell compartment composition and vitamin D status in MS patients, with particular interest for regulatory T cell functionality.

Ethical review	Approved WMO
Status	Completed
Health condition type	Autoimmune disorders
Study type	Observational invasive

Summary

ID

NL-OMON32188

Source
ToetsingOnline

Brief title
Vitamin D and T cells in MS

Condition

- Autoimmune disorders
- Central nervous system infections and inflammations

Synonym
MS, Multiple Sclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Multiple Sclerosis, Regulatory T lymphocytes, T lymphocytes, Vitamin D

Outcome measures

Primary outcome

Composition of the T cell compartment and vitamin D status

Secondary outcome

Functionality of regulatory T cell population

Study description

Background summary

Vitamin D is a potent immune modulator in vitro, which brings the T cell compartment in a less pro-inflammatory state. Hereby, low levels of the most prominent metabolite of vitamin D, 25-hydroxyvitamin D (25(OH)D), are associated with a high multiple sclerosis incidence and severity. From experimental animal studies, there are indications that a modulation of the T cell compartment is responsible for this association. (Smolders et al. Vitamin D as an immune modulator in multiple sclerosis, a review. J Neuroimmunol. 2008;194(1-2):7-17).

Study objective

The purpose of this study is to investigate the association between T cell compartment composition and vitamin D status in MS patients, with particular interest for regulatory T cell functionality.

Study design

Cross-sectional association study

Study burden and risks

The invasive intervention is the aquisition of 60cc blood by a venous puncture. The risk on side-effects (heamatoma or vagal reaction) is small and these side effects are passing things. For severely disabled patients, an additional journey to the hopsital can be aggrevating. Therefore, by request we visit the

patient at home for the venous puncture.

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

Clinical definite MS (McDonald criteria)
Relapsing Remitting clinical phenotype

Exclusion criteria

The use of other immune-modulating medicine than Interferon Beta

Recent start (<=0,5 year) of vitamin D supplementation

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	28-08-2008
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	27-05-2008
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL22666.096.08