

Vitamin D receptor expression in T cell subsets

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1) To investigate the VDR levels in different MS associated T cell subsets2) to compare the VDR levels in the different T cell subsets between MS patients and age and gender matched healthy volunteers

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

Summary

ID

NL-OMON33450

Source

ToetsingOnline

Brief title

Vitamin D receptor expression in T cell subsets

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, T cells, Vitamin D, Vitamin D receptor

Outcome measures

Primary outcome

The VDR expression levels will be determined both on the protein and mRNA level. VDR protein and mRNA levels will be measured in different MS-associated T cell subsets.

Secondary outcome

Next, VDR expression levels will be compared between RRMS patients and healthy volunteers.

Study description

Background summary

Auto-immune diseases, like multiple sclerosis (MS) are less frequent around the equator, where there is an equal amount of ultra violet B (UVB) radiation all year. Also, an association between the vitamin D status and MS is found. UVB-radiation is important for the vitamin D status and vitamin D influences immune regulation. The idea is that at higher latitudes (away from the equator) the vitamin D status is inadequate and that this influences immune regulation and makes healthy individuals more prone to develop MS. Vitamin D exerts its function via the vitamin D receptor (VDR). We hypothesize that a lower VDR expression can contribute to an increased susceptibility to develop MS. Therefore RRMS patients may have lower VDR levels in the different T cell subsets as compared to healthy volunteers.

Study objective

- 1) To investigate the VDR levels in different MS associated T cell subsets
- 2) to compare the VDR levels in the different T cell subsets between MS patients and age and gender matched healthy volunteers

Study design

cross sectional study

Study burden and risks

The only intervention that patients have to endure is a venepuncture. The most important risk of this is the development of a haematoma or a temporary vasovagal reaction. To decrease these risks, the venepuncture will be performed by a trained physician

Contacts

Public

Universiteit Maastricht

PO Box 616
6200 MD Maastricht
Nederland

Scientific

Universiteit Maastricht

PO Box 616
6200 MD Maastricht
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

Relapsing-remitting MS patients

between 20-40 years
female
use of exclusively interferon beta (> 2 months)

Exclusion criteria

use of immune modulatory drugs other than interferon beta

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2010
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO	
Date:	22-07-2009
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	NL28058.096.09