Study of immune parameters that may differ between HC and patients with MS : an explorative study

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to investigate functional characteristics of immune cells from MS patients, including migratory capacity, inflammasome activity and Breg cell function and compare these to healthy control subjects 2) to assess possible differences with regard to the...

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

Summary

ID

NL-OMON37483

Source
ToetsingOnline

Brief title
Study of immune parameters

Condition

- Autoimmune disorders
- Central nervous system infections and inflammations

Synonym
MS, Multiple Sclerosis

Research involving
Human

Sponsors and support

Primary sponsor: School for Mental Health and Neuroscience
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: inflammasome activity, migration, Multiple Sclerosis, supression

Outcome measures

Primary outcome

The main study parameters include the percentage of suppression of T cell proliferation, the percentage in reduction of either adhesion molecules or migrating immune cells and the secretion of IL-1*. Differences between MS patients and between MS patients and healthy controls will be investigated.

Secondary outcome

The effects of MS disease activity, type of disease and MS disease medication on functional immune cell characteristics

Study description

Background summary

Multiple Sclerosis is believed to be an auto-immune disease affecting the central nervous system. Auto-reactive T helper 1(Th1) and Th17 cells and a defect in the suppressive capacity of regulatory T cells (Treg) seem to be involved in disease pathogenesis. This defect in Treg suppressive function results in dysregulation of the effector cells and could therefore be important in disease pathogenesis. Next to T cells, also B cell suppressive function gained more interest during the last years in MS. Next to suppressive function, also migratory capacity of cells across the blood brain barrier is an important functional feature. In addition to the adaptive immune system, also the innate immune cells are involved in MS. One important feature is inflammasome activity. Therefore, we would like to perform a pilot study to explore different functional characteristics of immune cells, including Breg function, T cell migration across an endothelial barrier and inflammasome activity in MS patients. The results may give rise to more extended studies to confirm the data obtained in the proposed pilot study and could result in relevant functional targets for testing the efficacy of new treatment strategies in MS.

Study objective

to investigate functional characteristics of immune cells from MS patients, including migratory capacity, inflammasome activity and Breg cell function and compare these to healthy control subjects 2) to assess possible differences with regard to the functional characteristics of immune cells between different MS subtypes and between different treatment strategies.

Study design

This is a cross sectional explorative study.

Study burden and risks

The intervention that patients have to endure is a venepuncture. The most important risk of this the development of a haematoma or a vasovagal reaction. The risks of this intervention is minimal and of temporary nature.

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 between 18 and 65
Caucasian offspring

Exclusion criteria

MS patients: - Non- Caucasian offspring
- Use of immune suppressive medication;Healthy controls: - Non- Caucasian offspring
- Use of immune suppressive or immune modulatory medication
- Having MS or another autoimmune disease

Study design

Design

Study type:	Observational non 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):	26-04-2012
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	06-02-2012
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	NL38408.096.11