# The relation between neurodegeneration and other pathology in multiple sclerosis: an in vivo MRI study

Published: 03-08-2011 Last updated: 30-11-2024

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

# Summary

### ID

NL-OMON36150

**Source** ToetsingOnline

#### **Brief title**

The relation between neurodegeneration and other pathology in MS

### Condition

- Autoimmune disorders
- Demyelinating disorders

**Synonym** MS, multiple sclerosis

**Research involving** Human

### **Sponsors and support**

Primary sponsor: Vrije Universiteit Medisch Centrum Source(s) of monetary or material Support: Stichting MS research

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### Intervention

Keyword: multiple sclerosis, neurodegeneration, neuroimaging, pathology

### **Outcome measures**

#### **Primary outcome**

Global and local atrophy measures will be obtained from high resolution

T1-weighted images. Conventional MR images of the brain and spinal cord, and 3D

DIR images will be used to detect and classify MS lesions. Advanced MRI

techniques, namely DTI and T1 relaxation-time mapping, will be used to quantify

tissue damage in normal appearing brain tissue, and relations between these

parameters will be assessed.

### Secondary outcome

Not applicable.

# **Study description**

#### **Background summary**

Classically, multiple sclerosis (MS) has been approached as a \*typical\* inflammatory demyelinating disease of the central nervous system. Recent evidence has however suggested that neurodegeneration plays a critical role in the pathogenesis and severity of the disease. Unfortunately, to date the cause or starting point of neurodegeneration is unknown, and much is unclear about the variable phenotypic expression of neurodegenerative pathology in MS.

#### **Study objective**

The aim of this MRI study is to understand how neurodegeneration in MS (in vivo) is related to other facets of MS pathology, i.e. inflammatory (T2) lesions, black hole (T1) lesions, cortical lesions and damage of the normal appearing brain tissue. To achieve our goal, we propose to perform an extensive MRI study measuring different properties of the brain in the various disease phenotypes and study the relations between the observed neurodegeneration and

pathology globally, regionally and voxel-wise.

#### Study design

This study is a prospective, single-centre, observational cohort study assessing the relation between neurodegeneration and other pathology in patients with MS.

#### Study burden and risks

Participants are asked to come one day to our outpatient clinic to undergo an exam to determine EDSS (approximately 30 minutes) and an MRI scan. The scan will be made at our 3 Tesla MRI system and duration of the scan will be approximately 60 minutes. Earplugs will be provided to reduce the noise of the scanner. MRI examinations are considered to have negligible risks. Before the examination, all participants will be screened for metal objects in their bodies, risk of claustrophobia, or other MRI contraindications. No interventions will take place in this study.

# Contacts

#### Public

Vrije Universiteit Medisch Centrum

De Boelelaan 1117 1081 HV Amsterdam NL **Scientific** Vrije Universiteit Medisch Centrum

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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 18-65 years
- Clinically definite MS (based on Polman criteria, 2005)
- Need to meet the safety criteria to undergo an MRI examination

### **Exclusion criteria**

For all participants:

- History of drug abuse
- Psychiatric disease
- Claustrophobia
- Pregnancy
- Foreign non MR compatible metal objects in the body
- Foreign metal objects in or close to the head; Aditionally for the patients:
- Other neurological disorders besides MS
- Relapses and/or steroid treatment in the four weeks prior to the examination; Additionally for the healthy controls:
- Neurological disorders

# 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:	Diagnostic

# Recruitment

NL	
Recruitment status:	Completed
Start date (anticipated):	31-07-2012
Enrollment:	85
Туре:	Actual

# **Ethics review**

Approved WMO	
Date:	03-08-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC

# **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 CCMO ID NL36722.029.11