# Advanced MRI techniques and biomarkers to substitute gadolinium enhanced MRI for the detection of disease activity in multiple sclerosis.

Published: 14-08-2023 Last updated: 27-12-2024

1) To determine whether advanced MRI techniques can detect active inflammatory Gd enhancing lesions. 2) To determine whether blood biomarkers are associated with the presence of enhancing brain lesions in MS. 3) To determine whether advanced MRI...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Central nervous system infections and inflammations
Study type	Observational invasive

# Summary

### ID

NL-OMON53657

**Source** ToetsingOnline

Brief title ACTIVITY

### Condition

• Central nervous system infections and inflammations

**Synonym** Multiple Sclerosis

**Research involving** Human

### **Sponsors and support**

#### Primary sponsor: Amsterdam UMC

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Source(s) of monetary or material Support: Sticthing MS Research & Hersenstichting

#### Intervention

Keyword: Artificial Intelligence, Gadolinium-enhanced lesions, Multiple Sclerosis

### **Outcome measures**

#### **Primary outcome**

1) Establishing differences in image characteristics of Gd enhancing and

non-enhancing lesions on the advanced MRI sequences.

2) Establishing differences in image characteristics on the advanced MRI

sequences between new lesions and previously present lesions.

3) Establishing differences between blood biomarker levels between participants

with and without Gd enhancing lesions.

#### Secondary outcome

Not applicable.

# **Study description**

#### **Background summary**

Multiple sclerosis (MS) is characterized by active inflammatory lesions in the brain and spinal cord. These active inflammatory lesions are imperative for diagnostic and treatment purposes and can be detected by conventional MR imaging with the intravenous injection of Gadolinium (Gd) chelates. Several studies have made disconcerting reports of intracerebral deposition of Gd with repeated intravenous administration. Although the long-term consequences of this intracerebral deposition of Gd have not been identified, these findings have prompted the medical community to limit the use of IV Gd, as much as possible. This project aims to circumvent the use of intravenous Gd by studying alternative advanced MRI techniques and blood biomarkers to detect

active inflammatory Gd enhancing lesions of the brain in MS.

#### Study objective

1) To determine whether advanced MRI techniques can detect active inflammatory Gd enhancing lesions.

2) To determine whether blood biomarkers are associated with the presence of enhancing brain lesions in MS.

3) To determine whether advanced MRI techniques can distinguish between new recently active and older inactive lesions detected on high-resolution isotropic serial FLAIR images.

#### Study design

Prospective cross-sectional mono-center study.

#### Study burden and risks

This study will include a single study visit. Besides the burden of an extra visit to the hospital, the patients will undergo blood sampling and a brain MRI scan that is approximately 23 minutes longer than a routine clinical MRI of approximately 25 minutes. There will be no direct benefit for the participating patients. The group benefit will be the reduction of intravenous Gd injection and the associated long-term accumulation of Gd in body tissues for patients with MS. The blood sampling and brain MRI scan with intravenous gadolinium administration are of low risk, evidenced by extensive experience in daily clinical routine.

## Contacts

Public Amsterdam UMC

De Boelelaan 1118 Amsterdam 1081 HZ NL Scientific Amsterdam UMC

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# **Trial sites**

### **Listed location countries**

Netherlands

# **Eligibility criteria**

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

### **Inclusion criteria**

To be eligible for this study, the participant must meet the following criteria:

Diagnosed as CIS, RRMS, PPMS based on McDonald criteria (2017)

Adult (18-70 years old)

Signed informed consent

Separate inclusion criteria will be applied for the active and inactive subgroup:

For the active subgroup:

one or more Gd-enhancing lesion on brain MRI or signs of clinical disease activity

For the inactive subgroup:

no Gd enhancing lesion on brain MRI and no clinical signs of disease activity.

### **Exclusion criteria**

A potential participant will be excluded from the study based on the following criteria:

contra-indications for MRI

Pregnancy

History of (psychiatric) disorder which causes the patient to be incompetent to make a well-informed decision

Other concurrent neurological disease

# Study design

### Design

Study type: Observational invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Diagnostic	

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	17-11-2023
Enrollment:	75
Туре:	Actual

### Medical products/devices used

Generic name:	MR sequences. BBB-ASL
Registration:	No

# **Ethics review**

#### Approved WMO

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Date:	14-08-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-01-2024
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-10-2024
Application type:	Amendment
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 NL80209.018.23