A prospective longitudinal study of spinal cord lesions in multiple sclerosis: MRI monitoring and prognostic factors for active disease

Published: 12-03-2024
Last updated: 14-12-2024

We will prospectively collect spinal cord MRI data (in addition to routine brain MRI), and blood-based biomarkers (plus cerebral spinal fluid markers, if available), in recently diagnosed MS patients, to address the following research questions: 1…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Demyelinating disorders
Study type	Observational invasive

Summary

ID

NL-OMON56629

Source
ToetsingOnline

Brief title
MSpine

Condition

- Demyelinating disorders

Synonym
MS, multiple sclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Zuyderland Medisch Centrum

Source(s) of monetary or material Support: Nationaal MS Fonds

Intervention

Keyword: MRI, multiple sclerosis, prognosis, spinal cord

Outcome measures

Primary outcome

1. What is the incidence of asymptomatic spinal cord lesions in patients

commencing DMT?

2. In the absence of radiological progression on brain imaging, how frequently

do asymptomatic spinal cord lesions occur? In other words, how often is disease

activity solely proven by spinal cord MRI and what is the

number-needed-to-scan?

Secondary outcome

Secondary endpoints include which patient subgroups are prone to new spinal

cord lesions at follow-up in early disease.

Study description

Background summary

Multiple sclerosis (MS) is the most common demyelinating disease of the central nervous system and the most common cause of non-traumatic neurological disability in young adults. Magnetic resonance imaging (MRI) is the most important paraclinical investigation used in the diagnosis and monitoring of the disease. Over the past years, spinal cord MRI has improved significantly in quality and has become an important part of the diagnostic workup for MS. Presently, follow-up imaging of the spinal cord is only performed when spinal cord related symptoms occur. However, there is increasing evidence that asymptomatic spinal cord lesions can occur, independently of brain disease activity. Even though these spinal cord lesions may not exhibit symptoms, they have a lasting impact on the accumulation of disability over the long term. However, prospective data on the frequency and importance of asymptomatic

spinal cord lesions and therefore the potential role of spinal cord MRI in treatment monitoring, is lacking.

Study objective

We will prospectively collect spinal cord MRI data (in addition to routine brain MRI), and blood-based biomarkers (plus cerebral spinal fluid markers, if available), in recently diagnosed MS patients, to address the following research questions:
1 What is the incidence of asymptomatic spinal cord lesions in patients commencing DMT?
2 And in the absence of radiological progression on brain imaging, how frequently do asymptomatic spinal cord lesions occur? In other words, how often is disease activity solely proven by spinal cord MRI and what is the number-needed-to-scan?
A secondary objective is to investigate which patients are predisposed to developing new spinal cord lesions during follow-up in the early stages of the disease. For this question, we will focus on factors such as urinary tract symptoms, cerebrospinal fluid (CSF) profiles, lymfocyte composition in blood, soluble blood markers, and clinical features.

Study design

This will be a prospective longitudinal, observational study.

Study burden and risks

All study appointments will ideally be planned together with regular follow up visits, so patients will not have to visit the hospital additionally. Spinal cord MRI will add extra 45 minutes scanning time, which could lead to some (extra) discomfort, transient nausea, dizziness or a metallic taste. Blood withdrawals require 3 extra vials (21ml) withdrawal in addition to regular blood level controls. An extra venepuncture is only performed when necessary. Clinical tests are performed in regular follow up, only now performed more standardised and regularly. An additional questionnaire regarding urinary symptoms will be performed, which will take less than 5 minuts.This involves mainly prolonged appointment time. The risks and burdens are minimised as much as possible by combining regular follow up and scanning with study proceedings.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Patients diagnosed with relapsing-remitting MS (<5 years of first clinical event)
Patient between 18-65 years old
Treatment-naïve patients starting (a currently in the Netherlands approved) DMT (disease modifying treatment)

Exclusion criteria

Patients who are <18 years old
Patients who are >65 years old
Patients who presented first clinical event more than five years ago
Patients who have already started DMT
Patients who are incapable of giving informed consent
Patients who are unable to undergo local MRI scan, due to for instance:
Physical problems, for instance due to size/obesity (not fitting in regular MRI scanner), not being able to lie flat for extended periods of time (e.g. due to pain, shortness of breath). Due to claustrophobia.
Patients who have contraindications for MRI scan, for instance due to

MRI-unsafe or non-compatible implanted material/devices, such as pacemakers or ocular metal splinters, or patients who are pregnant at inclusion.

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):	06-08-2024
Enrollment:	155
Type:	Actual

Ethics review

Approved WMO Date:	12-03-2024
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	03-06-2024
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	02-12-2024
Application type:	Amendment
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	NL86278.096.24