

Longitudinal study of biological surrogate markers in primary progressive Multiple Sclerosis.

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

Summary

ID

NL-OMON31170

Source

ToetsingOnline

Brief title

Biological surrogate markers in primary progressive MS

Condition

- Demyelinating disorders

Synonym

MS

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: de stichting MS Research

Intervention

Keyword: Magnetic resonance imaging, Multiple Sclerosis, neuroaxonal damage, surrogate markers

Outcome measures

Primary outcome

To improve the sensitivity of surrogate markers for neuroaxonal damage for clinical trials by combining MR measures longitudinally.

To assess if any baseline measures of atrophy, NAA/Cr, MTI or DTI predicts a subgroup of patients who subsequently have greatest rates of atrophy.

Secondary outcome

To assess whether potential serum and urine biomarkers of neurodegeneration may have added value.

To produce data for powering neuroprotective studies for all of the different combinations of MR and biological fluid markers. This would allow selection of measures in the future depending on the study requirements.

To assess reproducibility and reliability of the data between centers.

Study description

Background summary

Patients with primary progressive multiple sclerosis represent a subgroup with clinical and MRI characteristics that differ from those of patients with relapsing-remitting multiple sclerosis / secondary progressive multiple sclerosis. They have less MRI lesion activity (lesion volume) and new lesions, more lesional neuroaxonal damage and less inflammation, more diffuse damage and spinal cord involvement. Thus, in PPMS patients the correlation between conventional MRI measures and clinical disease severity is poor.

Study objective

2 - Longitudinal study of biological surrogate markers in primary progressive Multip ... 5-05-2025

This study aims at investigating in vivo the macroscopic and microscopic aspects of brain and cervical cord neuroaxonal pathology in multiple sclerosis in a cohort of PPMS patients, by measuring brain and cervical cord atrophy, the ratio of N- Acetyl aspartate (NAA) and Creatine (Cr), magnetization transfer variables and diffusion tensor metrics. Such measures will assess cortical and subcortical structures * total brain, white and gray matter, thalamic, corpus callosum and cervical cord volumes or area, thalamic and corpus callosum NAA/Cr, whole brain, thalamic and corpus callosum MT measures, whole brain, thalamic and corpus callosum diffusion tensor metrics.

This study will also collect clinical data in the form of EDSS and MSIS-29 scores. Furthermore, in order to relate MRI parameters of neuroaxonal degeneration to body fluid markers of neuroaxonal degeneration, blood and urine samples will be collected

Study design

Patients and healthy controls will be studied at baseline, 2 , 50 and 52 weeks. MRI scanning will be performed. Disability will be assessed in patients using Kurtzke*s Expanded Disability Status Scale (EDSS) (Kurtzke, 1983) and the Multiple Sclerosis Impact Scale (MSIS -29) at the same time points. Blood and urine samples will be collected from patients and healthy controls at the same frequency as the imaging.

Study burden and risks

Subjects participating to this study will undergo four MRI scans. Also, on same occasions urine and venous blood will be collected. Lastly, only patients undergo each time a neurological exam and a selftest. This will all be done in one year.

There are practically no risks associated with participation with this study.

The burden of the study will be primarily the boredom or inconvenience of lying in a MRI scanner. Also, there is the burden of the needle (four times). Finally, patients also have the burden of being subject four times to a neurological exam and the selftest.

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

MS patients: disease type should be primary progressive and EDSS should be 0-6.5
Both patients and healthy controls should have an age between 18-60 years of age

Exclusion criteria

Immunomodulatory medication
Claustrophobia or other contraindications to MRI
Neurological or psychiatric disease or history

Study design

Design

Study type: Observational invasive

Intervention model: Other

Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-01-2008
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO	
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	ID
CCMO	NL19229.029.07