Multiple sclerosis lesion characterization on ultra-high-field MRI: Comparative pilot study of 9.4 vs 7 vs 3 tesla

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

Summary

ID

NL-OMON52035

Source
ToetsingOnline

Brief title
ULTIMS

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: Ministerie van OC&W

Intervention

Keyword: Brain, MRI, Multiple sclerosis, Ultra High Field

Outcome measures

Primary outcome

Difference in white matter lesion volume/count, cortical lesion volume/count, percentage of lesions with central veins, tolerability of the investigation, between the field strengths, quantitative image quality parameters (signal- and contrast-to- noise ratios).

Secondary outcome

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Study description

Background summary

Multiple sclerosis (MS) is the most common demyelinating disease in the central nervous system. Magnetic resonance imaging (MRI) has a prominent role in the diagnosis and monitoring of the disease and is the most suitable instrument for in vivo evaluation of MS pathology. In the past years there has been a vast amount of ultra-high field MRI research in MS, showing the potential benefits of its increased contrast- (CNR) and signal-to-noise ratio (SNR), allowing higher spatial resolution. These benefits include higher sensitivity in lesion detection including cortical grey matter lesions thanks to improved white/grey matter contrast. Additionally, specificity is increased because of better visualization of more MS specific pathological characteristics like the central vein sign, due to the increased susceptibility effects at higher field strengths combined with the aforementioned higher spatial resolution.

Study objective

In this pilot study, we aim to investigate if increasing field strength beyond 7T will result in additional advantages in characterization of MS lesions in vivo and to identify its limitations and technical challenges. More specifically, firstly, if this can potentially increase sensitivity for MS white as well as grey matter lesions. Secondly, if MS specific pathology, like

the central vein sign and paramagnetic rims, can be better visualized at higher compared to lower field strengths.

Study design

To scan 10 relapsing-remitting MS patients on a clinical field strength (3T) as well as ultra-high-field strengths (7T and 9.4T) at two time points (baseline and 6 months).

Study burden and risks

At baseline, patients will visit the MRI center to undergo a series of three scans at each of the field strengths on the same day. Each scan will take 5 to 15 minutes preparation time and we strive for an image acquisition time of around 30 minutes per scanner. This will be repeated after 6 months. Before the second scanning session, patients will visit the outpatient clinic for a regular follow up.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Inclusion criteria: Relapsing remitting MS patients (according to the 2017 McDonald criteria) between age 18-65 years, who had a new brain MRI lesion in the past 15 months. Choosing an upper limit of 65 years, limits the age-related vascular white matter lesion burden on the brain scans.

Exclusion criteria

Patients who are unable to undergo MRI investigations due to (i) non-compatible implanted material/devices or (ii) due to not being able to lie flat long enough because of another medical condition, will be excluded.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-09-2023
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO Date:	21-02-2022
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	NL79074.096.22