The importance of early brain changes in patients with MS with regard to cognitive and physical outcome

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28418

Source
NTR

Brief title
Temprano

Health condition

Relapsing-Remitting Multiple Sclerosis

Sponsors and support

Primary sponsor: Bristol Myers Squibb
Source(s) of monetary or material Support: Bristol Myers Squibb

Intervention

Outcome measures

Primary outcome

Changes in structural and functional MRI will serve as primary outcome measures, such as atrophy in the cortex and deep grey matter, changes in white matter damage in specific tracts and white matter and cortical lesions. Next, changes in functional brain measures will

be included, measuring for instance functional connectivity, eigenvector centrality mapping and functional brain adaptation.

Secondary outcome

Changes in cognitive performance (as measured with the neuropsychological examination) and clinical performance (as measured with the neurological examination) will serve as secondary parameters. Additionally, changes on questionnaires (e.g. arm and walk function, fatigue, anxiety and depression, subjective cognitive performance, coping style, mastery, stress, work participation and quality of life) will be included as other outcome measures. Molecular brain changes will also be investigated, addressing for example changes in GABA/glutamate and serum biomarkers NfL and GFAP.

Study description

Background summary

This 2-year prospective, longitudinal, single center, observational cohort study will be performed at the Amsterdam UMC, in which recently diagnosed MS patients will be followed over time with regard to cognitive and clinical performance, and structural and functional (imaging) measures. The study population consists of 120 recently diagnosed RRMS patients (6 to 12 months post diagnosis) and 60 matched healthy controls (HCs).

All participants in this study will visit the Amsterdam UMC, location AMC three times: at baseline, after 1 year and after 2 years. For the patients the visits will consist of a neurological examination, a neuropsychological examination, blood sampling (6 mL) and MR imaging (structural and functional). At home, patients will fill out several questionnaires on arm and walk function, fatigue, anxiety and depression, subjective cognitive performance, coping style, mastery, stress, work participation and quality of life. Additional blood samples (6 mL) will be drawn at month 3, month 6, month 9, month 15, month 18 and month 21. Healthy control subjects will undergo a similar protocol, except for the neurological examination.

Study objective

The main objective of this project is to identify the early brain changes in MS (i.e. patients that are recently diagnosed with RRMS) that can be measured by advanced structural and functional (network) imaging measures. Additionally, we will determine how and when these changes relate to clinical and cognitive decline and serum biomarkers. Finally, we will determine which of the measures is most predictive for clinical and cognitive decline in patients recently diagnosed with RRMS.

Study design

T0: first measurement, T1: at year 1, T2: at year 2.
Additional blood sampling every three months: month 3 (M3), month 6 (M6), month 9 (M9), month 15 (M15), month 18 (M18) and month 21 (M21).

Contacts

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Eligibility criteria

Inclusion criteria

1. Ability to understand the purpose and risks of the study and provide signed and dated informed consent and authorization to use protected health information (PHI) in accordance with national and local subject privacy regulations;
2. All participants should be 18-65 years of age;
3. Sufficient Dutch proficiency to be able to comprehend and to perform the neuropsychological examination;
4. All participants need to meet the safety criteria to undergo an MRI examination;

For the patients specifically:
5. Only patients that are recently (up to 12 months) diagnosed with clinically definite MS according to the 2017 revision of the McDonald MS criteria will be included;
6. Only patients with (active) relapsing-remitting disease course will be included;
7. All types of disease modifying treatment for MS are allowed.

Exclusion criteria

1. Unable or unwilling to provide informed consent;
2. Presence or history of alcohol or drug abuse;
3. Presence or history of psychiatric or neurological disease of the CNS (for patients:

neurological disease other than MS) that is expected to affect any of the outcome measures (will be discussed with the principal investigator and neurologist);
4. Presence of contra-indications for MRI;
5. Participation in other (scientific) studies using cognitive or physical training programs (interventions other than standard care) at baseline to avoid noise.

For the patient groups specifically:
6. Patients with disease categorized as clinically isolated syndrome, primary progressive, secondary progressive or progressive relapsing;
7. Relapses or steroid treatment less than four weeks prior to the visits. Visits of included patients experiencing a relapse will be postponed if possible;
8. Patients undergoing a cognitive relapse. Visits of included patients experiencing a cognitive relapse will be postponed if possible.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-02-2021
Enrollment:	180
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	26-07-2021
Application type:	First submission

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
NTR-new	NL9626
Other	METC VUMC : METC 2020.021 / ABR: NL72064.029.20

Study results