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

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|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Observationeel onderzoek, zonder invasieve metingen |

## Samenvatting

### ID

NL-OMON28418

**Bron**
NTR

**Verkorte titel**
Temprano

**Aandoening**

Relapsing-Remitting Multiple Sclerosis

### Ondersteuning

**Primaire sponsor:** Bristol Myers Squibb
**Overige ondersteuning:** Bristol Myers Squibb

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

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.

# Toelichting onderzoek

### Achtergrond van het onderzoek

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.

### Doel van het onderzoek

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.

### Onderzoeksopzet

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).

# Contactpersonen

## Publiek

Amsterdam UMC, locatie VUmc
Hanneke Hulst

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## Wetenschappelijk

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# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

# Onderzoeksopzet

## Opzet

| | |
|---|---|
| Type: | Observationeel onderzoek, zonder invasieve metingen |
| Onderzoeksmodel: | Anders |
| Toewijzing: | Niet-gerandomiseerd |
| Blindering: | Open / niet geblindeerd |
| Controle: | N.v.t. / onbekend |

## Deelname

Nederland

| | |
|---|---|
| Status: | Werving gestart |
| (Verwachte) startdatum: | 28-02-2021 |
| Aantal proefpersonen: | 180 |
| Type: | Verwachte startdatum |

## Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

**Wordt de data na het onderzoek gedeeld:** Nog niet bepaald

# Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 26-07-2021 |
| Soort: | Eerste indiening |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

| Register | ID |
|---|---|
| NTR-new | NL9626 |
| Ander register | METC VUMC : METC 2020.021 / ABR: NL72064.029.20 |

# Resultaten