PrograMS

No registrations found.

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

Summary

ID

NL-OMON21916

Source
NTR

Brief title
PrograMS

Health condition

Multiple Sclerosis

Sponsors and support

Primary sponsor: VU University Medical Center
Source(s) of monetary or material Support: Stichting MS Research (Dutch MS Research Foundation), grant number MS 18-358f

Intervention

Outcome measures

Primary outcome

Our primary outcome is longitudinal cognitive decline, as measured by neuropsychological assessment (NPE).

Secondary outcome

Our secondary outcome is clinical progression, defined by worsening physical disability

(EDSS). Parameters/predictors: Functional brain changes (functional MRI and magnetoencephalography, MEG); structural brain changes (MRI), ophthalmologic measurements (optical coherence tomography – OCT, and eye movements) and blood biomarkers.

Study description

Background summary

Single-center observational study, in which patients with MS and healthy controls who have previously participated in longitudinal studies at the MS Center Amsterdam are invited for a repeat visit, referred to as "Amsterdam MS cohort - round 2021". This will result in an unprecedented longitudinal MS cohort with advanced measurements (clinical, imaging and body fluid biomarkers) at three time points, roughly five years apart. The objective is to study underlying mechanisms of cognitive decline and clinical progression in MS and ultimately improve our understanding and prediction of clinical outcomes.

Study objective

By combining advanced modalities, a comprehensive model can be built for a better prediction of progression in MS.

Study design

Follow-up visit approximately 10-15 years after first observation (initiated at varying stages of the disease)

Contacts

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Eligibility criteria

Inclusion criteria

All people with MS and all healthy controls who have previously participated in the Presto (local ethics committee number: 2002/140), GeneOCT (2004/9), or LTD (2010/336) studies (collectively also known as the “Amsterdam MS Cohort”) and have not provided objection to be contacted for follow-up study, or have been enquired to join the cohort based on the Amsterdam MS Cohort (2020/269) protocol.

Exclusion criteria

MS patients unable to undergo the minimal data collection (as described in Methods section) or comorbidity that interferes with participation in this study (controls).

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-05-2021
Enrollment:	260
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	07-04-2021
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	NL9409
Other	METC VUmc : 2020.0601

Study results