Does MS grey matter pathology progress faster in regions with more damage in connected white matter?

No registrations found.

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

Summary

ID

NL-OMON23313

Source
NTR

Brief title
Rate of GM atrophy in MS

Health condition

multiple sclerosis; white matter damage; grey matter atrophy

Sponsors and support

Primary sponsor: VU University Medical Center
Source(s) of monetary or material Support: Dutch MS Research Foundation

Intervention

Outcome measures

Primary outcome

Three measures for WM damage will be assessed, i.e. lesion volume, lesion fractional anisotropy (FA) and NAWM FA, from which a composite WM damage score will be computed. High versus low WM damage scores will then be compared to the atrophy rates in the GM,

based on subcortical volume and cortical thickness measures. From this, we can compare atrophy rates of each GM structure from baseline to year 1 between the group of patients with higher damage in the WM tracts connected to that GM structure on the one hand, and the group of patients with lower damage in those WM tracts on the other.

Similar calculations will be performed between year 1 and year 2 in order to determine whether a larger increase of WM damage over the first study year is predictive of faster subsequent GM atrophy in the second year.

Secondary outcome

Next to the measures for GM and WM damage, resting state functional connectivity measurements will be used to assess whether GM and WM damage patterns effect the functional organization of the brain at rest, either prior to GM/WM damage, or following the damage patterns observed.
Furthermore, clinical parameters (see section 8.3) will be taken into account, in order to link the structural data to functionality of the brain in the RRMS patients.

Study description

Study objective

Our hypothesis is that MS grey matter pathology, and thereby disease burden and clinical outcome, can be better predicted by looking at damage in the connected white matter in early RRMS patients

Study design

Baseline (year 0), year 1 and year 2

Intervention

None

Contacts

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Eligibility criteria

Inclusion criteria

Patient group:

1. Minimum age 18 years

2. Clinically definite relapsing remitting MS for < 5 years

3. Either receiving no treatment, or receiving first line treatment for at least 6 months

4. Expanded Disability Status Score (EDSS) ≤ 5.0

5. Written informed consent

Control group:

1. Minimum age 18 years

2. Written informed consent

Exclusion criteria

1. Past or current clinically relevant non-MS neurological or psychiatric disorder(s)

2. Past or current clinically relevant (auto)immune disorder(s)

3. Treatment for MS with first line therapy for less than 6 months

4. Treatment for MS with second line therapy

5. Relapse and/or steroid treatment in past 3 months

6. Pregnancy

7. MRI incompatibility, e.g. metal objects in or around the body, claustrophobia or inability to lie still in the scanner

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2016
Enrollment:	55
Type:	Anticipated

Ethics review

Positive opinion

Date:	04-10-2016
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	NL5923
NTR-old	NTR6103
Other	METc VUmc : 2016.314

Study results