Effects of dimethyl fumarate (Tecfidera) on white matter integrity and functional brain adaptation and cognition in Multiple Sclerosis

No registrations found.

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

Summary

ID

NL-OMON21490

Source
NTR

Brief title
TBA

Health condition

Relapsing-Remitting Multiple Sclerosis

Sponsors and support

Primary sponsor: Biogen
Source(s) of monetary or material Support: Biogen

Intervention

Outcome measures

Primary outcome

The primary objective of the study is to investigate changes in white matter structural

integrity in patients with relapsing remitting multiple sclerosis (MS) after a different treatment duration with Tecfidera (i.e 6 months, 12 months, 18 months, and 30 months).The primary endpoint that relates to this objective is change from baseline (or previous time point) in diffusion tensor imaging measures (fractional anisotropy and mean diffusivity).

Secondary outcome

Secondary objectives are the effects of Tecfidera (over time) on: structural brain damage, functional connectivity, brain activation patterns during fMRI task, physical disability and cognitive decline, brain metabolite concentrations.

Study description

Background summary

This clinical observational, single center study will be performed at the VU University Medical Center in Amsterdam. The study population consists of 60 RRMS patients (n=30 starting on Tecfidera, n=30 using Tecfidera for ~1 year) and 30 healthy controls. Neuropsychological and neurogical assessments as well as questionnaires and a (f)MRI-scan will be performed at baseline, after 6 months and 18 months, to longitudinally look at the short- and long time effects of Tecfidera treatment on the brain and cognition in MS.

Study objective

We expect to see improved white matter integrity (i.e. estimated by increased fractional anisotropy, decreased mean diffusivity) in response to Tecfidera treatment. As a result physical functioning might improve, cognitive functioning will be stable (in cognitively intact patients) /improve (in cognitively impaired patients). Stronger effects are expected after a longer duration of treatment.

Study design

T0: first measurement, T1: at 6 months, T2: at 18 months

Intervention

N/A

Contacts

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Eligibility criteria

Inclusion criteria

1) ability to understand purpose of the study and provide informed consent
2) 18-65 years old
3) need to meet safety criteria to undergo MRI-scan
4) sufficient visual acuity and motor skills to perfom fMRI task
5) patients with RRMS
6) if using other drugs influencing CNS, they need to be stable on this medication at least for 6 months.

Exclusion criteria

1) unable/unwilling to provide informed consent
2) presence/history psychiatric or neurological disease (other than MS for patient group) that may affect outcome measures
3) contra-indication for MRI
4) history/presence alcohol/drug abuse
5) participation in other studies using cognitive or physical training programs to avoid noise.

For patient groups specifically:
6) PPMS or SPMS
7) relapse and steroid treatment 4 weeks < examination

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-04-2018
Enrollment:	90
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	08-08-2019
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	NL7944
Other	METC VUMC : METC 2017.469 / ABR: NL63236.029.17

Study results