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

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

Samenvatting

ID

NL-OMON21490

Bron
NTR

Verkorte titel
TBA

Aandoening

Relapsing-Remitting Multiple Sclerosis

Ondersteuning

Primaire sponsor: Biogen
Overige ondersteuning: Biogen

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

N/A

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	10-04-2018
Aantal proefpersonen:	90
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:	08-08-2019
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	NL7944
Ander register	METC VUMC : METC 2017.469 / ABR: NL63236.029.17

Resultaten