Effect of dimethyl fumarate (Tecfidera) on the association between fatigue and fatigability in relapsing-remitting MS patients*

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The aim of this study is to investigate the effects of DMF (Tecfidera) on the association between fatigue and fatigability measures in pwRRMS starting with DMF medication.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Central nervous system infections and inflammations
Study type	Interventional

Summary

ID

NL-OMON44334

Source
ToetsingOnline

Brief title
Tecfidera and Fatigue and fatigability in RRMS / DMF_FF_RRMS

Condition

- Central nervous system infections and inflammations

Synonym
relapsing-remitting multiple sclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W,Biogen

Intervention

Keyword: Dimethyl fumarate, Fatigability, Fatigue, Relapsing remitting multiple sclerosis

Outcome measures

Primary outcome

Association between fatigue (as measured with the FSS questionnaire) and measures of fatigability (changes in index finger abductor force and voluntary activation) in pwRRMS after 16 weeks of Tecfidera medication.

Secondary outcome

Secondary study parameters are: 1. changes in the decline in voluntary, electrically evoked force and muscle activation during the fatiguing task (fatigability measures), and 2. changes in FSS scores after 16 weeks of Tecfidera medication (fatigue measures).

Study description

Background summary

Fatigue is an important symptom in persons with relapsing-remitting multiple sclerosis (pwRRMS) which negatively affects quality of life.
Previous research showed that the perception of fatigue was associated with the force decline during a 2-minute sustained contraction.

Dimethylfumarate (DMF) is a first-line oral MS drug prescribed by neurologist as disease modifying therapy for pwRRMS. Beside an anti-inflammatory, an anti-oxidative response is described for DMF and it is our hypothesis that the inflammatory response in pwMS is an important contributor to fatigue in pwMS. If during treatment with DMF the association between the perception of fatigue and force decline exists and continues to exist, will this observation open the possibility to use force decline as a means to objective fatigue.

Study objective

The aim of this study is to investigate the effects of DMF (Tecfidera) on the

association between fatigue and fatigability measures in pwRRMS starting with DMF medication.

Study design

Single-blinded prospective experimental study. Investigators are blinded for the group and session number

Intervention

Twee-minute contraction with the index finger abductor muscle.

Study burden and risks

Participant are measured 4 times during a 2-minute contraction. The measurements take about 1.5 hours. During the contraction the nerve will be electrically activated; no risks are associated with this stimulation but the stimulation feel a little painful (like touching a electrical fence).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Informed consent
* Age: 18 * 55 years
Additional criteria for pwRRMS:
* A diagnosis of RRMS according to the McDonald criteria
* A baseline Expanded Disability Status Scale <4.5
* Newly initiating treatment with DMF (Tecfidera) under routine clinical care
* Adequate hand function that allows subjects to utilize the force transducer (as determined by the neurologist).

Exclusion criteria

* History of alcohol or drug abuse or current alcohol or drug abuse
* Neurologic condition unrelated to MS Psychiatric disorder (including affective disorders).
* Other conditions/diseases influencing fatigue:
o Chronic fatigue syndrome
* Primary immunodeficiency.
* Treatment with steroids within one month prior to inclusion
* Participation in an investigational drug study within 3 months prior to inclusion
* A MS relapse within one month prior to inclusion
* Medication:
o 4-aminopyridine or another form of fampridine
o antidepressant

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-12-2018
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	04-05-2018
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
CCMO	NL62864.042.17
Other	NTR 28290