Tecfidera and Fatigue and fatigability in RRMS

No registrations found.

Ethical review	Positive opinion
Status	Other
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25337

Source
Nationaal Trial Register

Health condition

Fatigue, Fatigability, relapsing-remitting multiple sclerosis, force, dimethyl fumarate

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: Biogen

Intervention

Outcome measures

Primary outcome

Description of the association between measures of fatigability and fatigue in pwRRMS after 16 weeks of treatment with dimethyl fumarate (Tecfidera).

Secondary outcome

1) Description of the effect of 16-week treatment with DMF on fatigue as quantified with the Fatigue severity scale (FSS) in pwRRMS. 2) Description of the effect of 16-week treatment with DMF on fatigability as quantified by a decline in muscle force and changes in voluntary

drive in relapsing-remitting MS patients.

Study description

Background summary

Fatigue is an important symptom in persons with relapsing-remitting multiple sclerosis (pwRRMS) which negatively affects quality of life. Fatigue is a self-reported symptom quantified with questionnaires. In previous studies (6, 7) we showed that fatigue is strongly associated with force decline (normalised for maximal force and mood) during a fatiguing task. This opens the possibility to use force decline as a means to objectify fatigue. Dimethylfumarate (DMF) is a first-line oral MS drug prescribed by neurologists as disease modifying therapy for pwRRMS. It is the aim of this study to investigate the association between fatigue and fatigability in pwRRMS starting with DMF medication.

Study design

experimental measurements are performed 2 weeks before treatment with DMF; at the start and after 4 and 16 weeks of treatment.

Intervention

2-minute sustained index finger abduction

Contacts

Public
Dept Neuroscience, Section Medical Physiology, HPC-FB43
University Medical Center Groningen

C.A.T. Zijdewind
Ant. Deusinglaan 1 P.O.Box 196
Groningen 9713 AV
The Netherlands
+31503616438
Scientific
Dept Neuroscience, Section Medical Physiology, HPC-FB43
University Medical Center Groningen

C.A.T. Zijdewind
Ant. Deusinglaan 1 P.O.Box 196
Groningen 9713 AV
The Netherlands
+31503616438

Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

• Informed consent

• Age: 18 – 55 years

• Adequate hand function that allows subjects to utilize the force transducer (as determined by the neurologist)

Additional inclusion criteria for pwRRMS:

• Newly initiating treatment with DMF (Tecfidera) under routine clinical care

• A diagnosis of RRMS according to the McDonald criteria

• A baseline Expanded Disability Status Scale <4.5

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

• 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 controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	01-01-2018
Enrollment:	20
Type:	Unknown

Ethics review

Positive opinion

Date:	01-12-2017
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	NL6947
NTR-old	NTR7203
Other	: UMCG-2017--367

Study results