

# 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.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Central nervous system infections and inflammations
<b>Study type</b>	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**

Two-minute contraction with the index finger abductor muscle.

### **Study burden and risks**

Participants 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 feels a little painful (like touching an electrical fence).

## **Contacts**

### **Public**

Universitair Medisch Centrum Groningen

Hanzeplein 1  
Groningen 9700AV  
NL

### **Scientific**

Universitair Medisch Centrum Groningen

Hanzeplein 1  
Groningen 9700AV  
NL

## **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