Tecfidera and Fatigue and fatigability in RRMS

Gepubliceerd: 01-12-2017 Laatst bijgewerkt: 18-08-2022

Ethische beoordeling	Positief advies
Status	Anders
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25337

Bron
Nationaal Trial Register

Aandoening

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

Ondersteuning

Primaire sponsor: University Medical Center Groningen
Overige ondersteuning: Biogen

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

2-minute sustained index finger abduction

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Anders
(Verwachte) startdatum:	01-01-2018
Aantal proefpersonen:	20
Type:	Onbekend

Ethische beoordeling

Positief advies

Datum:	01-12-2017
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	NL6947
NTR-old	NTR7203
Ander register	: UMCG-2017--367

Resultaten