

Relation between subjective and motor fatigue in MS patients

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Is subjective fatigue in patients with MS related to a combination of force reduction during a fatiguing task and depression score?

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Demyelinating disorders
Study type	Interventional

Summary

ID

NL-OMON36518

Source

ToetsingOnline

Brief title

Relation between subjective and motor fatigue

Condition

- Demyelinating disorders

Synonym

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

Intervention

Keyword: Motor fatigue, MS, Subjective fatigue

Outcome measures

Primary outcome

The primary study parameters are force reduction during the fatiguing task and the scores on the questionnaires.

Secondary outcome

Maximaal voluntary force

Study description

Background summary

Fatigue is one of the most common complaints for patients with MS, and it often has a strong influence on daily living. However, fatigue is a broad concept. Motor fatigue is commonly measured during research, for example after a fatiguing motor task. Until now, research has failed to find a relation between fatigue as it is reported by patients on questionnaires, and the fatigue that is measured during a fatiguing task (Romani et al, 2004; Surakka et al, 2004; Sheean et al, 1997; Sharma et al, 1995). Previous research in our department, however, seems to have found that subjective fatigue correlates with the scores on the HADS and with a fatiguing motor task, when the latter one is corrected for gender and maximal force (Steens et al, unpublished data). Together, these two measurements explain approximately 70% of subjective fatigue. Further research in a larger group of patients is needed in order to verify this data.

Study objective

Is subjective fatigue in patients with MS related to a combination of force reduction during a fatiguing task and depression score?

Study design

During the study, three questionnaires are administered and the fine motor skills are determined. The force (using a force recorder) of the right index finger abductor (FDI) are measured, while the subject is asked to deliver maximal force during two minutes.

Intervention

Fatiguing task

Study burden and risks

No risks, time investment for the subject is 1 hour.

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

Relapsing remitting MS
EDSS <5,5
Sufficient hand function to operate the force recorder
Right handedness

Informed consent

Exclusion criteria

Psychiatric disorder
Depression
Neurological disorder other than MS
EDSS $\geq 5,5$

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated): 01-08-2010

Enrollment: 100

Type: Actual

Ethics review

Approved WMO
Date: 23-06-2010
Application type: First submission
Review commission: METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO
Date: 31-08-2011
Application type: Amendment
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	NL32501.042.10