

Fatigue after mild traumatic brain injury

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How important is fatigue in patients with MTBI? What are the mechanisms underlying the decline in force during a fatiguing task? Which changes in brain activation take place during the fatiguing task?

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

Summary

ID

NL-OMON41347

Source

ToetsingOnline

Brief title

Fatigue-MTBI

Condition

- Demyelinating disorders

Synonym

braininjury

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: brain injury, EMG, fatigue, fMRI

Outcome measures

Primary outcome

The main parameters are: decline in force, changes in voluntary activation during the fatiguing task. Time-course of brain activation during the fatiguing task. Score on questionnaires.

Secondary outcome

Is 'sense of fatigue' associated with maximal force, force decline and sense of depression (mood) in patients after MTBI?

Study description

Background summary

Fatigue is an often reported symptom by patients after a traumatic mild brain injury (TMBI). This fatigue is months (> 6 months; van der Naalt 1999,2001) after the accident still present and deteriorates the patients well-being. Sensation of fatigue is often measured with questionnaires (eg. fatigue severity scale, FSS).

In patients with multiple sclerosis fatigue is also an often reported and debilitating symptom. In this patients group we demonstrated that fatigue has both motor as well as mood related characteristics (Steens et al, 2012a en b; METc 2008-003). By performing the same experiments in patients with MTBI and to compare the data with control subjects and with data obtained in MS patients we hope to get more insight in the mechanisms that are responsible for the increased feeling so fatigue in different patients groups.

Naalt van der J (2001). Prediction of outcome in mild to moderate head injury: a review. J Clin Exp Neuropsychol 23: 837-851.

Naalt van der J, van Zomeren AH, Sluiter WJ, Minderhout JM (1999). One year outcome in mild to moderate head injury: the predictive value of acute injury characteristics related to complaints and return to work. J Neurol Neurosurg Psychiatry 66:207-213.

Steens A, de Vries A, Hemmen J, Heersema T, Heerings M, Maurits N, Zijdwind I (2012a). Fatigue perceived by Multiple Sclerosis patients is associated with muscle fatigue. Neurorehab Neural Repair 26: 48-57.

Steens A, Heersema T, Maurits N, Renken RJ, Zijdwind I (2012b). Mechanisms underlying muscle fatigue differ between multiple sclerosis patients and controls: a combined electrophysiological and neuroimaging study. *Neuroimage* 59: 3110-3118.

Study objective

How important is fatigue in patients with MTBI? What are the mechanisms underlying the decline in force during a fatiguing task? Which changes in brain activation take place during the fatiguing task?

Study design

This research comprises experiments in which brain activation, force, muscle activity and muscle activation by the brain is studied. During the experiments subjects are asked to fill out 3 questionnaires (2 fatigue-related and 1 mood related questionnaire). During the first session in the Dept Neuroscience subjects are asked to produce a force with their hand muscles. Simultaneously with the voluntary activation the nerve is stimulated with a short electrical pulse.

The second session takes place in an 3-Tesla MR scanner. Subjects are in the and produce again force with their handmuscles. The force and muscle activity are measured with MR compatible force transducer and electrodes. The nerve is stimulated with MR-compatible surface electrodes.

By combining all the data information is obtained about changes in the brain during fatiguing contractions/

Study burden and risks

No risk; short painful sensation during electrical stimulation of the nerve. During the MR session subjects have to lay still for one hour in the scanner. Total time investment 2* 2 hours.

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

age: 20-75

Glasgow Coma scale at intake: 13-15

good hand function

sense of fatigue 3 month after accident

Exclusion criteria

addiction to drugs or alcohol

psychiatric disorder

earlier traumatic brain injury

other neurological disorder

other fatigue related disorder

fmri-related exclusion criteria

Study design

Design

Study type:

Observational invasive

Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2013
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO	
Date:	21-05-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO	
Date:	05-03-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO	
Date:	15-12-2016
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	NL42398.042.13