

Relation between cognitive and motor fatigue in patients with a functional stroke mimic or acute ischemic infarction*

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Does performance on a fatiguing dual task task in patients with FSM decline more compared to patients with AIS? What are the differences in cognitive functioning and motor fatigue between FSM, AIS and healthy controls? What is the relation between...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Central nervous system vascular disorders
Study type	Interventional

Summary

ID

NL-OMON49453

Source

ToetsingOnline

Brief title

Fatigue in FSM and AIS

Condition

- Central nervous system vascular disorders

Synonym

Functional stroke mimics, stroke

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Acute ischemic infarction, Fatigue, Functional stroke mimic

Outcome measures

Primary outcome

Performance on the two-choice reaction time task (CRT): reaction times, and number of errors; during and after the fatiguing motor task.

Secondary outcome

- Anxiety and Depression scores (HADS)
- Fatigue questionnaire scores (DMFS, FSS, MFIS)
- Side strongest hand
- Difference stimulated maximum force and voluntarily delivered maximum force.
- Baseline characteristic; sex and age.

Study description

Background summary

In functional neurologic disorders the function of the nervous system is disturbed without structural damage. Patients with functional disorders can present with acute stroke-like symptoms, this is called a functional stroke mimic (FSM). Fatigue is a major problem in functional neurologic disorders and in acute ischemic stroke (AIS). In this study we want to gain more insight into the interaction between motor and cognitive fatigue. Studies in healthy controls have shown that during a dual-task (DT), a cognitive task combined with a fatiguing motor task, the performance on a cognitive task declines over time (with fatigue). We hypothesise that in patients with a functional stroke mimic and patients with AIS this interaction is stronger compared to healthy controls. We also want to study whether the symptoms and the interaction between cognitive and motor fatigue recover with time. Our group has already

performed this dual-task in patients with MS. (METc 2010-150)

Study objective

Does performance on a fatiguing dual task task in patients with FSM decline more compared to patients with AIS? What are the differences in cognitive functioning and motor fatigue between FSM, AIS and healthy controls? What is the relation between fatigue questionnaire scores and performance on the cognitive and motor tasks? How does the performance on the dual-task change after a year in FSM and AIS?

Study design

The study design is a mono-centre intervention study. Subjects perform a cognitive task: a two choice reaction time task (CRT). The CRT is performed on its own, and simultaneously with a motor task (i.e. the dual-task). Patients and controls will be measured at two time points, 6 weeks and 12 months after admission to the hospital. At each time point the investigation comprises two sessions of one and a half hour, on two separate days. Force and muscle activity (EMG) of the first dorsal interosseous muscle (FDI) are measured during every session. During the force measurement the ulnar nerve will be stimulated electrically. The maximal squeeze force will be measured in both hands using a squeeze force gauge.

Intervention

nvt

Study burden and risks

There are no risks involved. Time investment for subjects is 2 x 2 x 1.5 hours (6 hours).

Contacts

Public

Selecteer

Hanzeplein 1
Groningen 9700 RB
NL

Scientific

Selecteer

Hanzeplein 1
Groningen 9700 RB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- * Age: 18-67 years
- * For patients: Diagnosis of functional stroke mimic or AIS
- * In patients with AIS: NIHSS <10 at presentation.
- * Good hand-function
- * Right-handedness

Exclusion criteria

- * Drugs or alcohol addiction
- * Psychiatric disorder
- * Neurologic disorder other than FSM or AIS
- * Impaired hearing

Study design

Design

Study type: Interventional

Intervention model: Other

Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	21-08-2020
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO	
Date:	18-05-2020
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO	
Date:	16-09-2020
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	NL72758.042.20