Cortical mechanisms of stroke induced glenohumeral subluxation: a transcranial magnetic study

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The aim of this study is to compare the integrity of the corticospinal tract and cortical reorganization of shoulder girdle muscle representations in chronic stroke patients with and without GHS as well as healthy controls.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Central nervous system vascular disorders
Study type	Observational non invasive

Summary

ID

NL-OMON37808

Source
ToetsingOnline

Brief title
Shoulder subluxation after stroke

Condition

- Central nervous system vascular disorders

Synonym
Cerebro Vascular Accident, Stroke

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cortical reorganisation, Glenohumeral subluxation, Stroke, Transcranial magnetic stimulation

Outcome measures

Primary outcome

Main study parameters are TMS induced motor evoked potentials (MEPs) and the

extent of the motor surface map.

Secondary outcome

not applicable

Study description

Background summary

In 2004, 216.500 inhabitants of the Netherlands had to live with the consequences of stroke. The increase of life expectancy and the development of medical science will result in a higher prevalence of stroke survivors. The consequences of stroke (impairments and disabilities) have a major impact on, among other things, the activities of daily living. Glenohumeral subluxation is one of the consequences of stroke. Subluxation makes the shoulder vulnerable to injuries, causes a reduced use of the arm, hinders the rehabiliation process and may become painful, thus creating a vicious circle. Current mechanisms that explain glenohumeral subluxation use a musculoskeletal perspective. However, these mechanisms are under strong debate. Until now, persistent glenohumeral subluxtion has never been studied or explained by the role of coritcal changes that occur after stroke. Transcranial magnetic stimulation (TMS) is a non-invasive method that applies magnetic pulses over the skull, causing depolarisation of nerve fibers in the cortex. When this stimulation is done over the motor cortex, the role of this cortex can be assessed with regard to persistent glenohumeral subluxation.

Study objective

The aim of this study is to compare the integrity of the corticospinal tract and cortical reorganization of shoulder girdle muscle representations in chronic stroke patients with and without GHS as well as healthy controls.

Study design

This is a cross-sectional study

Study burden and risks

The estimated invested time per person is 1 hour and a half. To ensure that subjects with increased risk for TMS application are excluded for the study, a TMS questionnaire will be used. Persons will only be admitted to the study after medical approval by dr Pijlman. Risks of unfavourable effects induced by TMS in this study is not to be expected for healthy subjects or stroke patients. Although some participants report transient headache.

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

Subjects will be chronic stroke patients (time post stroke between 6 months and 10 years), with (n<=12) and without (n<=12) glenohumeral subluxation. All patients are able to give their informed consent. The age-matched control group exists of healthy subjects without stroke (n<=12). All subjects are between 45 and 75 years old.

Exclusion criteria

The exclusion criteria for the stroke paitents are:
- Pre-stroke shoulder damage or disorder that may interfere with glenohumeral subluxation or the ability to activate shoulder girdle muscles.
- A history of epilepsy, severe aphasia, implanted electrical devices, metal implants in close proximity to the TMS coil.
- Pregnancy, brain tumour, brain infection, medication that potentially lowers seizure treshold.
The exclusion criteria for the healthy controls are:
- Any acquired brain injury
- Shoulder damage or disorder.
- A history of epilepsy, severe aphasia, implanted electrical devices, metal implants in close proximity to the TMS coil.
- Pregnancy, brain tumour, brain infection, medication that potentially lowers seizure treshold.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	05-06-2012
Enrollment:	36
Type:	Actual

Medical products/devices used

Generic name:	Transcranial Magnetic Stimulation
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	04-01-2012
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL38578.068.11