Somatosensory deficits after stroke

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

Summary

ID

NL-OMON36259

Source
ToetsingOnline

Brief title
BODIES

Condition

- Central nervous system vascular disorders

Synonym
CVA, Stroke

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: NWO

Intervention

Keyword: Body ownership, Body representation, Somatosensory, Stroke

Outcome measures

Primary outcome

Performance on neuropsychological examination

Secondary outcome

Performance on elaborate somatosensort examination

Study description

Background summary

The somatosensory system is important for many common everyday activities and informs the brain about the position of different parts of the body. When this information about the representation of the body is processed, it not only allows recognition of body parts, but also allows to move within and act upon the environment. These processes are higher order, cognitive aspects of the somatosensory system. Somatosensory deficits after stroke are common and related to a longer length of stay and lower activity levels during rehabilitation. However, extensive neuropsychological somatosensory functioning after stroke is only rarely assessed. As a result, knowledge about the occurrence of these deficits, their underlying neurological substrates as well as the influence of these deficits on outcome remains unclear. The overall aim of this study is to increase our understanding of the cognitive processes, the underlying neuroanatomical substrate and its recovery processes of higher order somatosensory deficits after stroke. This may provide new opportunities for development of rehabilitation programs.

Study objective

There are two objectives for this study.
1. To investigate the frequency of somatosensory deficits in the early and chronic stage of stroke patients.
2. To understand the nature and the neuroanatomical correlates of specific higher order somatosensory deficits

Study design

This is a longitudinal observational study in which a battery of validated non-invasive neuropsychological tests will be administered to look into somatosensory functioning in the early and chronic phase of patients with a

stroke. In addition, other cognitive domains that are associated with somatosensory functioning such as visual perception, language, executive functioning and memory are also assessed, to control for interference of other cognitive domains. The aim of the study is to investigate the frequency and the course of somatosensory deficits after stroke. In addition, the nature and underlying neurological substrate of higher order somatosensory deficits will be investigated.
This study will be performed on 60 hospital-based patients in the early phase after the diagnosis of a stroke in the University Medical Center Utrecht (UMCU). To minimize the burden for the participants, data collected by a standard 'care as usual' neuropsychological assessment will be used for the patients hospitalised in the UMCU. This standardised neuropsychological assessment already tests several cognitive domains, including visual perception, language, executive functioning, memory and also includes a short screening on somatosensory functioning. This neuropsychological assessment is a standard procedure and is administered in all ischemic stroke patients. In case patients show deficits on the initial short somatosensory screening or report complaints in the somatosensory functions (for example, show a decreased sense of touch or report problems in recognizing one's own arm of hand), we propose to conduct an elaborate somatosensory testbattery targeting the full somatosensory domain which also include tasks for higher order somatosensory functions. Finally, all participants who underwent an elaborate somatosensory assessment will be tested for a follow-up assessment after six months to explore the course of the deficits.

Study burden and risks

The patient is asked to concentrate for 90 minutes of testing in the early phase after stroke and 2 hours of testing after 6 months on tests that examines cognitive functions. The tests are all standardised pen- and paper test that are designed for a clinical population. However, a posiible burden for the patients might be fatigue due to concentration. To diminish the fatigue, several breaks are included. Previous studies which are comparable with respect to nature and testmaterial did not have shown any adverse effects or complaints (for example, the study with protocolnumber 05-109 "Perception and action in the somatosensory system")

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

Somatosensory/body representation deficits or complaints
Suffered from a recent stroke (<2 weeks)
Patients must be 18 years or older;
Neurological deficits must be the consequence of a stroke;
Lesions must be visible on a CT- or MRI scan;
Written informed consent

Exclusion criteria

Not able to communicate in Dutch or severe global aphasia;
History of alcohol or drug abuse;
Neurological disorders other than (sub)cortical lesions
Psychiatric disorders which could affect / have affected cognitive function;
Any other non-neurological disorder influencing cognitive functioning;

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2012
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	12-07-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL32864.041.11