EXplaining PLasticity after stroke

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Primary objective: to assess cortical activity post stroke in a repetitive way to determine cortical involvement in dedicated motor tasks and to relate cortical activity to clinical outcome prospectively after stroke. Secondary objective: to assess...

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

Summary

ID

NL-OMON39598

Source
ToetsingOnline

Brief title
EXPLORE-stroke:

Condition

- Central nervous system vascular disorders

Synonym
Cerebrovasculair Accident CVA, Stroke

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Hersenstichting Nederland

Intervention

Keyword: Cortico-muscular coherence, Plasticity, Rehabilitation, Stroke

Outcome measures

Primary outcome

primary: cortico- muscular coherence, i.e. the concordance between brain and muscle activity at different brain areas, expressed as a fraction

Secondary outcome

Secondary: clinical outcome as measured by the Action Research Arm Test (ARAT), Motricity Index (MI) of arm and leg, Fugl-Meyer for the arm (FM-arm), Erasmus modification of the Nottingham Sensory Assessment (EmNSA), Letter Cancellation Task (LCT), Nine Hole Peg test (NHPT), a structured participant interview of real arm use using the Motor Activity Log (MAL), Stroke Impact Scale (SIS version 3.0) and Nottingham Extended ADL (NEADL).

Study description

Background summary

Current post stroke upper limb rehabilitation is unable to work beyond fixed functional recovery patterns. Yet, functional MRI scanning reveals that the post-stroke brain is plastic, i.e. alternative brain areas are recruited. To make uses of the potential that brain plasticity has to offer, changes of brain activity need to be measured repetitively during motor tasks in the stroke recovery phase. State-of-the-art signal recording equipment and processing techniques bring this goal within reach.

Study objective

Primary objective: to assess cortical activity post stroke in a repetitive way to determine cortical involvement in dedicated motor tasks and to relate cortical activity to clinical outcome prospectively after stroke. Secondary objective: to assess reliability (test-retest) and validity (differences between patients and healthy subjects) a of a concise measurement protocol extracted out of existing protocols, that can easily be used in a clinical setting.

Study design

Prospective study: repeated measures (assessments at fixed time intervals in the post stroke recovery phase) and a within subjects factor, i.e. stroke patients with a good respectively poor prognosis for arm function recovery; cross sectional study with repeated measures for the second objective

Study burden and risks

Meaurements bear minimal risks. Patients and control subjects are asked to do concentrated work for some time during which forces have to be exerted on a haptic wrist manipulator. Patients within the prospective study are asked to undergo a measurement session for in total five times. Wishes and possibilities of patients, family and therapists are taken into account as much as possible when sceduling the appointments. Patiens and control subjects within the cross-sectional study are asked to undergo the measurements one more time after the initial visit.

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

regarding the primary objective: 1) an upper limb deficit, i.e. a NIHSS score of 1-4 in the second week post stroke; 2) a first-ever ischemic lesion in the territory of the MCA, verified by CT and/or MRI scan; 3) age between 40 and 75 years; 3) written or oral informed consent; 4) be able to sit for 30 seconds without support. Regarding the secondary objective: patients > 1 year post stroke with a motor deficit of the upper extremity NHSS *1; healthy volunteers within expected age range of stroke survivors, i.e. 40-75 years.

Exclusion criteria

1) a pacemaker or other metallic implants; 2) upper extremity orthopaedic limitations; 3) not being able to communicate i.e. < 4 points on the
Utrecht Communication Observation; 4) a Mini Mental State Examination, MMSE score of 22 points or less and 5) successful recombinant tissue plasminogen activator (rTPA, or alteplase) treatment.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-08-2012

Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	07-03-2012
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	22-05-2014
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL39323.058.12