

4D-EEG: Uncovering the neurological mechanisms behind upper limb functional recovery after stroke

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25135

Source

Nationaal Trial Register

Brief title

4D-EEG

Health condition

Ischemic Stroke, ischemic CVA.
Hersen infarct, beroerte

Sponsors and support

Primary sponsor: VUmc

Source(s) of monetary or material Support: European Research Council Advanced Grant. Project no. 291339

Intervention

Outcome measures

Primary outcome

Action Research Arm Test & Fugl-Meyer scores.

Secondary outcome

Location of task related cortical electrical activity during various experimental paradigms in MRI coordinates. fMRI activity maps during various experimental paradigms. TMS maps. DTI tract.

Study description

Background summary

Rationale:

Stroke is a major cause of disability in the developed world. Up to 80% of the stroke patients suffer an upper limb paresis. Only one one-third of those patients regain some dexterity, leaving the majority with disabilities in activities of daily living. (Dobkin et al. 2005; Kwakkel 2003). Little is known of the mechanisms behind functional recovery. Much of our knowledge on neuroplasticity and its mechanisms is derived from animal studies. Ways to assess neuroplasticity in humans are in an early developmental phase. In order to make true progress, the next step is to assess the dynamics of cortical activity in a larger cohort of patients, covering the entire possible phenotype from patients with an initial good to poor prognosis and longitudinal in time. In order to develop additional evidence based therapies, a better understanding of underlying brain dynamics is essential. To this end, accurate mapping of brain network connectivity and localization is needed.

Objective:

The 4D-EEG study aims to elucidate the underlying mechanisms of upper limb functional recovery using portable EEG (electroencephalography) methodology as well as clinical measures of motor function. The following questions are asked: How do true neurological restitution and substitution contribute to upper limb recovery? What changes occur in the brain when patients show recovery of upper limb capacity? Do these changes contribute to better function or do they result from decreased cortical inhibition? Does early EEG provide additional value in prediction algorithms of functional outcome of upper limb dexterity? And finally, how does the cortical spinal tract integrity affect the functional outcome?

Study design:

Projects:

A. Cross-sectional study: Relate our EEG methodology to fMRI (functional magnetic resonance

imaging).

B. Prospective cohort study: Repeated application of our EEG method in the first six month post stroke.

C. Cross-sectional study: Cortical spinal tract (CST) integrity and its relation with functional recovery. Using trans cranial magnetic stimulation (TMS) & diffusion tensor imaging (DTI) measurements

Study population:

A. Chronic stroke patients (i.e. > six months post stroke), age ≥ 18 years old
+ Age matched control subjects. (N*=21, C*=10).

B. First ever stroke patients, 1-3 weeks post stroke, age ≥ 18 years old. (N=50).

C. Sub-acute stroke patients (i.e. five-six months post stroke), age ≥ 18 years old
+ Age matched control subjects. (N=21, C=10).

*C = Number of control subjects, *N = Number of Patients

Intervention

Not applicable, all three projects are observatory hence all subjects will receive normal rehabilitation care according to the guidelines.

Main study parameters/endpoints:

The main endpoint of project A is the validation of the source localization of EEG cortical activity in relation to the local oxygen metabolism as measured with fMRI. The corresponding parameter is the displacement in millimeters MRI space. The first application of our protocol in project A to stroke patients will be used to compile a feasible experimental paradigm for the prospective cohort study. Although the repeatability of the experiments has already been verified in pilot-experiments, the sensitivity of the novel outcome parameters to stroke pathophysiology needs to be established prior to the prospective cohort.

The main endpoint of the prospective cohort study (B) is the longitudinal relationship, between, on the one hand dexterity and feedback properties of the upper limb motor system and on the other hand, observed changes in cortical dynamics related to movement. The main study outcome of project C is the correlation between CST integrity and functional outcome.

Study objective

The dynamics of motor task related cortical electrical activity will be related to the outcome of upper limb function after stroke

Study design

Project A & C are cross-sectional with one time point.

Prospective cohort project B:
weeks 1-5, 8, 12 & 26 post stroke

Intervention

Not applicable: The study does not interfere with patients' normal care according to the guidelines. The healthy control subjects will not receive treatment.

Contacts

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Eligibility criteria

Inclusion criteria

All subjects: Age ≥ 18 years old all both genders and races.

Patients Project A: Chronic single ischemic stroke > six months prior to inclusion.
Patients Project B: Acute single ischemic stroke < three weeks prior to inclusion.
Control subjects Project A & C: Age matched to patients

Exclusion criteria

Pacemaker or other metallic implants
Neurological conditions besides stroke that may interfere with the outcome
Orthopedic limitations of upper limb that may interfere with the outcome
Medication in past 3 months may interfere with the outcome

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-11-2013
Enrollment:	91
Type:	Anticipated

Ethics review

Not applicable	
Application type:	Not applicable

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
NTR-new	NL4084
NTR-old	NTR4221
Other	: 291339
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A