4D * EEG: a new tool to investigate the spatial and temporal activity patterns in the brain during stroke rehabilitation

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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-OMON47437

Source
ToetsingOnline

Brief title
4D * EEG

Condition

- Central nervous system vascular disorders
- Embolism and thrombosis

Synonym
cerebrovasculair accident, Stroke

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: European Research Council Advanced

Grant. Project no. 291339.

Intervention

Keyword: Biomarkers, Cerebrovascular accident, EEG, fMRI, Neural networks, Prognostic models, Stroke, System indentification

Outcome measures

Primary outcome

Action Research Arm Test

Location and network properties of movement related cortical electrical

activity.

Physical properties of the paretic upper limb

Cortical electrical activity in response to medial nerve stimulation

Resting-state EEG power

Microstructural and connectivity changes during brain repair post stroke.

Secondary outcome

Ashworth Score

Frenchay Arm Test

Motricity index

Brunnstrom Fugl Meyer arm/hand test

Nine Hole Peg Test

Erasmus MC Modification of the (revised) Nottingham Sensory Assessment

Stroke Impact Scale version 3.0

Nottingham Extended ADL

Motor Activity Log

O-Letter Cancellation Test

Barthel Index

Pittsburgh Sleep Quality Index / Epwort Sleepiness Scale

Study description

Background summary

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.

Study objective

The 4D-EEG study aims to elucidate the underlying mechanisms of upper limb functional recovery using high density portable
EEG (electroencephalography) methodology as well as clinical measures of motor function. The following questions are addressed:
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:
A1. Cross-sectional study: Relate our EEG methodology to fMRI (functional magnetic resonance imaging).
A2. Cross-sectional study: Assess the construct validity of the NeuroFlexor
A3. Cross-sectional study: Development of an EEG amplitude calibration

procedure
B1. Prospective cohort study: Repeated application of our EEG method in the first six month post stroke.
B2. Prospective cohort study: Longitudinal changes in neuromechanic parameters in the first six months 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
D) Prospective cohort study: Longitudinal changes in neuroanatomical parameters in the first six months post stroke.

Study burden and risks

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. Little is known of the mechanisms behind functional recovery. Much of our knowledge on neuroplasticity and its mechanisms is derived from animal studies. In order to make true progress, the next step is to assess the dynamics of cortical activity in a larger cohort of patientsAll the proposed experiments are no-invasive and safe.

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

*First-ever ischemic stroke in an area supplied by the anterior, medial, and/or posterior cerebral arteries, mono-or hemiparesis, age over 18

Exclusion criteria

pacemaker or other metallic implants, previous existing orthopedic limitations of upper limb that would affect the results, botuline-toxine injections or medication that may influence upper limb function in past 3 months.

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:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-04-2015
Enrollment:	195
Type:	Actual

Ethics review

Approved WMO Date:	16-06-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-08-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-10-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-04-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-04-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-10-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-05-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL47079.029.14