Lesion conductivity and its effect on transcranial direct current stimulation

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The objective of this study is:- to estimate the electrical conductivity of the chronic stroke lesion and the variance on this within chronic stroke subjectsSecondary:- derive functional organisation of the motor system of the upper extremity…

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

Summary

ID

NL-OMON49749

Source
ToetsingOnline

Brief title
Assessment of chronic CVA lesion conductivity

Condition

- Central nervous system vascular disorders

Synonym
cerebrovascular accident, stroke

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: STW,Rijndam Revalidatie,Rijndam Revalidatie; TMSi,TMSi

Intervention

Keyword: cva, lesion, stroke, tDCS

Outcome measures

Primary outcome

- Electrical conductivity of the lesion, estimated per individual patient

Secondary outcome

- Functional motor area, estimated per individual

Study description

Background summary

Motor impairments are frequent after stroke. Transcranial direct current stimulation is a way that could possibly improve motor rehabilitation after stroke. In clinical studies with stroke patients, mixed results are found, however, possibly due to a one-fits-all approach which is not valid for stroke patients. Dependent on the lesion location and size and the functional reorganisation, the brain stimulation has to be applied differently. At the moment it is not clear from literature what the influence of the lesion is on the electric field that is generated by the brain stimulation. To improve brain stimulation, more knowledge on this is required.

Study objective

The objective of this study is:

- to estimate the electrical conductivity of the chronic stroke lesion and the variance on this within chronic stroke subjects

Secondary:
- derive functional organisation of the motor system of the upper extremity through EEG, using fMRI as a reference

Het doel van dit onderzoek is:

- te bepalen wat de elektrische geleidbaarheid van de laesie is en wat de variabiliteit hierop is binnen chronsiche cva patiënten

Secundair:
- het middels EEG bepalen van de functionele organisatie van het motorisch systeem van de bovenste extremiteit, met fMRI als referentie

Study design

Observational, exploratory study

Study burden and risks

Low risk: the MRI, as well as the tDCS, EEG and the motor tasks form no risks on the health of the participant.

The MRI will be recorded by the radiology department of Erasmus MC. All recordings will be performed according to existing protocols.

The tDCS will be applied on subclinical intensity, such that participants will unlikely notice anything from the stimulation. The application of tDCS on clinical intensity has been verified to be safe and of negligible risk.

EEG is a safe, non-invasive form to measure brain signals

The burden for participants is a time investment of 4 hours in total, divided over 2 sessions (1 hour for the first session, 3 hours for the second session)

Due to the low burden and low risk of the study, we think performing this study is justified.

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

- Capable to perform a simple motor task with the hand

For the stroke patients:
- Ischemic stroke at least 6 months before the experiment starts
- Reduced (but not absent) motor function

Exclusion criteria

- Implants or metal parts in head/body
- Usage of medication or drugs that affect the nervous system
- Pregnancy
- Not capable to perform a simple motor task
- Unable to understand the instructions
- Epilepsy
- Alcoholism
- Cognitive impairment or (history of) psychiatric disorders
- Hemineglect
- Claustrophobia

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:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2020
Enrollment:	20
Type:	Anticipated

Medical products/devices used

Generic name:	transcranial direct current stimulation
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	10-02-2020
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL70630.078.19