Late LTP-like plasticity effects of tDCS in chronic stroke patients

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Identify the effect of late LTP-like plasticity tDCS in chronic stroke patients on skill learning 24 hours later.

Ethical review	Approved WMO
Status	Pending
Health condition type	Central nervous system vascular disorders
Study type	Interventional

Summary

ID

NL-OMON40977

Source
ToetsingOnline

Brief title
tDCS-LPCS

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: ZonMW en Stichting Coolsingel

Intervention

Keyword: Chronic stroke patients, Motor learning, Plasticity, tDCS

Outcome measures

Primary outcome

The main objective of the study is to determine the effect of late plasticity tDCS on skill learning 24 hours later. As a motor learning paradigm, we will use a circuit tracking task which chronic stroke patients perform better if tDCS is applied concurrently. During this task, patients have to trace a cursor over a circuit as fast and accurate as possible by moving a computer mouse. Skill will be quantified by calculating a combined speed/ accuracy score and compared between sham, conventional unpaired tDCS, conventional paired tDCS and late LTP-like plasticity tDCS groups.

Secondary outcome

• To compare excitability changes following late plasticity tDCS in stroke patients with concurrent tDCS stimulation and sham stimulation

• To identify improvement in arm/ hand functions unrelated to skill learning and generalization of skill learning to a new circuit with the same arm/hand.

• To determine the main effect of several polymorphisms known to be involved in plasticity on skill learning.

• To determine if skill learning with the unaffected arm correlates with skill learning with the affected arm.

Study description

Background summary

About 80% of stroke patients suffer motor impairments, but current therapies have very limited effects on motor recovery. Therefore, investigating new

potential therapeutic approaches is crucial. Transcranial Direct Current Stimulation (tDCS) is a form of non-invasive electrical stimulation where a weak current is applied through electrodes over the scalp. This stimulation is known to (1) induce changes in neuronal excitability -which can last up to one day with late LTP-like plasticity protocols- in a polarity and site-specific manner, and (2) facilitate motor learning and stroke recovery. However, it is unknown how the motor cortex excitability changes that follow tDCS relate to the increased learning/ recovery potential. The currently upheld hypothesis is that motor learning needs to be synchronized in time with electrical stimulation, but recent results from our lab suggest that tDCS also increases skill learning after stimulation has ended. If this is true, tDCS has a much larger therapeutic window and is a more valuable clinical tool than currently believed. Therefore, we want to investigate how late plasticity tDCS affects the increase in skill learning normally seen with tDCS when applied 24 hours before training. The outcome of this study can provide important guidelines on effective motor therapy during stroke rehabilitation.

Study objective

Identify the effect of late LTP-like plasticity tDCS in chronic stroke patients on skill learning 24 hours later.

Study design

Double-blinded, randomized between-subjects trials.

Intervention

tDCS will be administered with a CE-certified stimulator (DC-Stimulator Plus, neuroConn, Germany; CE 0118). The different stimulation protocols are: 30 seconds stimulation at t=0 and t=34 minutes (sham), 20 min. anodal bihemispheric stimulation and 30 seconds of sham stimulation at t=36 minutes (conventional tDCS) and 10 min. anodal - 25 min. pause - 10 min. anodal bihemispheric stimulation (late LTP-like plasticity tDCS). All stimulation sessions include a 30 second ramp-up and a 30 second ramp-down period to ensure comfort.
With regards to blinding, all stimulation protocols will run for 47 minutes during which the device will show the impedance between the two electrodes. Second, it is possible to program the device for each participant, ensuring that the participant and experimenter are blinded for experimental condition.

Study burden and risks

Before start of the experiments, subjects provide a sputum sample to assess the presence of the common BDNF and COMT polymorphisms.

Subjects will undergo low frequency transcranial magnetic stimulation (days 1, 2 and 9) and transcranial direct current stimulation (days 1 and 2) of the motor cortex and will perform several motor tasks (days 1, 2 and 9). At the end of each experiment, a questionnaire on discomfort and concentration will be handed for the subjects to fill out.

tDCS will be administered with a CE-certified stimulator (DC-Stimulator Plus, neuroConn, Germany; CE 0118). The different stimulation protocols are: 90 seconds stimulation (sham), 20 min. anodal bihemispheric stimulation (conventional tDCS) and 10 min. anodal - 25 min. pause - 10 min. anodal bihemispheric stimulation (late plasticity tDCS).

Subjects will be asked not to drink coffee on the day of the experiments because this could influence motor cortical excitability.

There will be financial compensation for expenses related to participation.

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

Chronic (> 6 months) stroke patient
Aged 18-80 years
Motor deficit in the upper limb due to the stroke

Exclusion criteria

Being unable to perform the task or to understand the instructions/ apraxia
Presence of intracranial metal
Epilepsy
Alcoholism
Cognitive impairment, or psychiatric disorder
History of psychiatric disorders
Taking acute or chronic psychoactive drugs
Absence of recordable MEPs after TMS
Hemineglect

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2014

Enrollment:	80
Type:	Anticipated

Medical products/devices used

Generic name:	Transcranial Direct Current Stimulator
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	24-07-2014
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	NL48838.078.14