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

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Identify the effect of late LTP-like plasticity on motor rehabilitation during the subacute phase after stroke.

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

Summary

ID

NL-OMON40946

Source
ToetsingOnline

Brief title
tDCS-LPSS

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: Plasticity, Rehabilitation, Subacute stroke patients, tDCS

Outcome measures

Primary outcome

To investigate whether late LTP-like plasticity tDCS increases the

effectiveness of upper limb rehabilitation therapy after stroke.

Secondary outcome

• To investigate whether the application of tDCS in subacute stroke patients

increases quality of life, cognitive performance and depression.

• To investigate whether late LTP-like plasticity tDCS increases the

effectiveness of lower limb rehabilitation therapy after stroke.

• To investigate the safety, side effects and drop-out rates for tDCS as an

integral part of upper limb rehabilitation in the first months post stroke.

Study description

Background summary

About 80% of stroke patients suffer motor impairments, but current therapies have 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. So far, several pilot studies have reported beneficial results from tDCS in both subacute and chronic stroke patients, but it*s still unclear how tDCS should be repeated over multiple days to optimally enhance recovery and training effects. Using a late LTP-like plasticity protocol could increase effectiveness of standard clinical care rehabilitation sessions and thus enhance the effects of rehabilitation. Therefore, we want to investigate how late LTP-like plasticity tDCS affects rehabilitation in subacute stroke patients. 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 on motor rehabilitation during the subacute phase after stroke.

Study design

Double-blinded, randomized between-subjects trials.

Intervention

Patients who are enrolled in this study will receive standard care with the addition of two one hour tDCS sessions (sham or real stimulation) per week for 4 weeks.

Study burden and risks

All participants are stroke patients who are enrolled in Rijndam*s regular stroke rehabilitation programme. In addition to regular treatment, tDCS is applied twice a week for 50 minutes during which patients are allowed to watch television, read a book or have breakfast. Furthermore, extra measurements include arm and hand motor skill tests (T0-T4), questionnaires on quality of life, depression and cognitive performance (T0 and T3-4) and a genetic analysis.

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

• Subacute stroke (within 1-3 weeks post stroke)
• Acute hemiparesis with single thromboembolic non-hemorrhagic infarction documented by a neurologist
• Aged 18-79

Exclusion criteria

• Absence of recordable MEPs from the ADM after TMS
• Absence of voluntary movement (MRC < 2)
• Head injury or the presence of intracranial metal or intracranial lesions
• History of cranial irradiation
• History of epilepsy
• Presence of a pacemaker
• Taking anticonvulsant or neuroleptic medication
• Substance abuse
• Inability to understand instructions
• History of psychiatric disorders

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):	01-11-2014
Enrollment:	48
Type:	Anticipated

Medical products/devices used

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

Ethics review

Approved WMO Date:	05-12-2014
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	NL49887.078.14