The offline effects of transcranial direct current stimulation (tDCS) on postural balance control after stroke.

Published: 12-11-2015
Last updated: 15-05-2024

The objective of this study is twofold.One aim of the study is to investigate the effects of tDCS (anodal, cathodal and sham) on balance correcting responses and simple reaction times in lower extremity muscles. We will determine whether the effects...

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

Summary

ID

NL-OMON42035

Source
ToetsingOnline

Brief title
Effects tDCS after stroke

Condition

- Central nervous system vascular disorders

Synonym
CVA, stroke

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: balance, MRI, stroke, tDCS

Outcome measures

Primary outcome

Influence of tDCS (anodal, cathodal and sham) and group differences on:

- muscle onsets of the primovers measured by EMG in lower extremity movements

- quality of balance responses (leg angle of the step leg)

Influence on the effect of tDCS by:

- MRI based measures (DTI) of structural integrity of the corticoreticular

pathway and the corticospinal tract

Secondary outcome

- Influence of tDCS (anodal, cathodal and sham) on muscle amplitudes of the

prime movers measured by EMG in lower extremity movements

- Relation between the effecs of tDCS and functional (step onset) and clinical

outcomes

- Other MRI related outcomes, as functional connectivity in relation to the

effects of tDCS on the lower extremity movments

Study description

Background summary

In people after stroke, responses to external perturbations are delayed, which is a main risk factor for falling. In the last decades, transcranial direct current stimulation (tDCS) has been shown to facilitate executed movements in stroke survivors. However, this has almost exclusively been studied in upper

extremity movements. In young adults, tDCS has recently been shown to facilitate balance recovery responses in the lower extremities as well. This study will investigate to what extent the latter results also apply to people after stroke. In this population, a wide variability in effects of tDCS is reported for upper extremity movements, which is expected to be due to the amount of cortical integrity after the CVA. Therefore, this study will also investigate the relation between the effects of two types of stimulation (anodal over the affected hemisphere, and cathodal over the unaffected hemisphere) and MRI obtained values for cortical integrity of the motor regions.

Study objective

The objective of this study is twofold.
One aim of the study is to investigate the effects of tDCS (anodal, cathodal and sham) on balance correcting responses and simple reaction times in lower extremity muscles. We will determine whether the effects of tDCS are different between people after stroke and healthy controls (within similar age range and in young controls).
Another goal is to investigate whether neuroimaging based measures of integrity of neural motor pathways can explain the anticipated variability of tDCS-induced effects in people after stroke.

Study design

randomized single-blind sham-controlled cross-over study

Study burden and risks

Participants will not directly benefit from their participation in the study. MRI scans are painless and safe. MRI is a technique without radiation (unlike x-ray and CT scans). In case of unexpected findings, the participant will be informed by his physician. Transcranial direct current stimulation (tDCS) is a widely used non-invasive brain stimulation technique, applying weak direct currents via conductive sponge electrodes to the scalp. These weak currents can slightly shift the neurons* membrane potential and thereby increase or decrease spontaneous neuronal activity in the stimulated cortex, but (unlike TMS) they do not evoke action potentials. During the stimulation, participants may transiently experience light tingling, itching or burning sensations on the skin underlying the electrodes, which can be unpleasant. The most common side effects are a light transient headache and a feeling of fatigue. In the current study, participants will be stimulated with a protocol that is considered safe with respect to the latest published safety guidelines. All subjects are screened for their relevant medical history and other tDCS safety aspects (e.g. metal parts in the head, skin allergies). Postural responses will be assessed on the Radboud Falls Simulator. Participants will be exposed to balance

perturbations by sudden translations of the support surface. There are no risks of participating in the balance assessment, since rails are mounted around the balance platform and participants wear a safety harness. From previous studies at our department, we know that people (after a CVA) should be able to overcome the balance perturbations at the proposed intensity. In summary, because the risk is negligible and the burden associated with participation can be considered minimal, we do not expect serious adverse events due to the project.

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

Only people over 18 years old in the chronic phase after experiencing a supratentorial unilateral stroke (> 6 months in the past) that resulted in hemi pareses will be recruited for this study. Furthermore, healthy controls of similar age and with a similar male:female ratio

will be enrolled in the study and 10 healthy young controls (18 - 30 year) are included for the tDCS sessions only.

Exclusion criteria

• Serious head trauma or head, neck or shoulder surgery in the past
• Large or ferromagnetic metal parts in the upper body (except for dental fillings and wire)
• Implanted cardiac pacemaker or neurostimulator (too close to the head) or Venous Access Port
• Pregnancy
• Skin diseases at intended electrode sites (tDCS or EMG electrodes)
• Any prescribed medication that can alter cortical excitability (e.g. anti epileptics, tricyclic anti-depressives or benzodiazepines) within two weeks prior to participation.
• Participated in a TMS or tCS study less than 1 year ago.
• Suffering from claustrophobia
• Suffering from epilepsy
• Irremovable piercing or medical patch
• Any neurological or orthopaedic disorder (other than stroke) that may interfere with the MRI outcomes of interest and/or with the performance on the movement tasks
• Disorders of hearing, which cannot be corrected to normal.
• Medication negatively affecting balance or reaction times (e.g. neuroleptics, antidepressants, anticonvulsants, sedatives)
• Severe cognitive impairment (mini mental state examination (MMSE) <24)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-01-2016

Enrollment:	45
Type:	Actual

Ethics review

Approved WMO Date:	12-11-2015
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 20568
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL51735.091.15
OMON	NL-OMON20568
OMON	NL-OMON24501

Study results

Date completed:	22-06-2017
Actual enrolment:	37