The effect of non invasive brain stimulation on lower limb motor control

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

Summary

ID

NL-OMON38314

Source
ToetsingOnline

Brief title
Effect brain stimulation on lower limb

Condition

- Central nervous system vascular disorders

Synonym
cerebrovascular accident, Stroke

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Twente
Source(s) of monetary or material Support: ZONMW Veni subsidie toegekend aan Edwin van Asseldonk

Intervention

Keyword: excitability, gait, stroke, tDCS

Outcome measures

Primary outcome

The main study parameter is the relative change in single pulse Motor Evoked Potential (MEP) of the Tibialis Anterior and Vastus Lateralis at the post measurements compared to the baseline measurement.

Secondary outcome

Secondary parameters are change in intermuscular coherence between the Vastus Lateralis and Biceps Femoris, intramuscular coherence of the Tibialis Anterior, change in propulsion of the paretic leg, change in basic gait parameters, change in H-reflex of the Soleus, change in reciprocal Ia inhibition of the soleus and change in D2 inhibition at the post measurements compared to baseline.Other parameters are the leg portion of the Fugl Meyer score, the 10 m walk test, the Functional Ambulation Categories and the motricity index

Study description

Background summary

Stroke is the leading cause of disability in the western world. About 70% of the 41.000 individuals who suffer a first-ever stroke annually in the Netherlands are not able to walk independently after a stroke. Although these people show some recovery, recovery is often incomplete and the process is long and labor-intensive.

Recovery is largely dominated by reorganization of surviving brain elements, also called cortical plasticity. Brain stimulation with weak electric currents, transcranial direct current stimulation (tDCS), induces plasticity and enhances motor function. At present, evaluations of this technique only considered arm

function.

Study objective

The primary objective is to assess the effect of tDCS using different electrode configurations on corticomotor excitability in the lower extremities of chronic stroke survivors and healthy subjects.

Secondary objectives are (a) to assess the effect of tDCS using different electrode configurations on coordinated motor output, spinal excitability and corticomotor drive in the lower extremities of chronic stroke survivors and healthy subjects, (b) assess the relation between tDCS induced changes in corticomotor excitability as assessed with TMS and changes in corticomotor drive as assessed with inter- and intramuscular EMG coherence in healthy subjects and stroke survivors,(c) assess the relation between the tDCS induced changes in corticomotor excitability and motor functions of stroke survivors as assessed with clinical scales.

Study design

This study is a double blind cross-over study. All subjects participate in 3 experimental sessions separated by one week. In all sessions both, subjects and raters, will be blinded to the applied intervention. The order of the interventions will be randomized between subjects.

Intervention

In each of the three experimental sessions a different form of stimulation will be applied being uni-hemisphere anodal stimulation, dual-hemisphere stimulation or sham (placebo) stimulation. The tDCS will be applied for 10 minutes and different tests will be performed before (baseline) and after the stimulation (post) to assess the effects of the stimulation condition.

Study burden and risks

Participants will have to visit the laboratory three times with a minimum of one week between the different visits. Each of the sessions will take about 3 hours. The applied techniques to modulate and assess corticomotor excitability are generally well tolerated. Possible side-effects and risks are described in section 9.4 of the research protocol.

Stroke survivors and the healthy subjects will likely not have any direct benefit from participation. We do not expect that the stimulation results in any long lasting effects. It is of importance to conduct this study to know whether tDCS results in any beneficial short lasting effects. If so, in future studies we can try to turn these short lasting effects in long lasting effects

by applying tDCS on subsequent days or combine it with motor training. The tests in healthy subjects are performed to assess and understand the effects of tDCS when all corticospinal tracts are intact.

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

For healthy subjects
- age>18 years;For stroke survivors
- diagnosed with a hemiparesis as the result of a first ever, ischemic stroke
- chronic stage: time since stroke > 6 months
- independent walkers with clear walking impairment

Exclusion criteria

- contraincidation to TMS or tDCS
- other neuromuscular disorder or orhopedic problems
- have a history of cardiac conditions that interfere with physical load

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-08-2011
Enrollment:	20
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO

Date:	22-02-2011
Application type:	First submission
Review commission:	METC Twente (Enschede)

Approved WMO Date:	27-08-2012
Application type:	Amendment
Review commission:	METC Twente (Enschede)

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: 29069
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL34235.044.10
Other	TC=2729
OMON	NL-OMON29069