De offline effecten van hersenstimulatie (type tDCS) op balanshandhaving na een beroerte. / The offline effects of brain stimulation (type tDCS) on balance control after stroke.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20568

Source
Nationaal Trial Register

Brief title
Effects tDCS after stroke

Health condition

stroke, CVA, beroerte

Sponsors and support

Primary sponsor: Radboudumc, Nijmegen, The Netherlands
Source(s) of monetary or material Support: Radboudumc, Nijmegen, The Netherlands

Intervention

Outcome measures

Primary outcome

The main outcome variable is the reaction time in a simple reaction time task and the onset of postural responses.

Secondary outcome

Relation between the effects of tDCS and structural imaging markers in stroke survivors.

Study description

Background summary

Transcranial direct current stimulation (tDCS) is a noninvasive brain stimulation technique that alters cortical excitability. In a previous study was shown that anodal tDCS facilitates balance recovery responses in young healthy people. Here, we investigate whether facilitation of balance responses also occurs in people after stroke. Furthermore, we investigate the effect of cathodal tDCS on the same balance responses and the relation between tDCS effects and structural imaging markers.

Study objective

Transcranial direct current stimulation (tDCS) is a noninvasive brain stimulation technique that increases (anodal tDCS) or decreases (cathodal tDCS) cortical excitability. We hypothesize that anodal tDCS shortens latencies of responses during both simple reaction time tasks and balance recovery responses. We do not expect that cathodal tDCS will shorten these motor responses. Furthermore, we hypothesize that the effects of tDCS will be more variable in people after stroke compared to healthy controls.

Study design

week 1: Intake measurement (stroke participants)

week 2: MRI scan (stroke participants)

week 3: tDCS measurement 1 (stroke and control participants)

week 4: tDCS measurement 2 (stroke and control participants)

week 5: tDCS measurement 3 (stroke and control participants)

Intervention

transcranial direct current stimulation (tDCS); 2mA for 15 minutes. Anodal, cathodal and sham stimulation will be applied on M1 in a random order across participants.

Contacts

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Eligibility criteria

Inclusion criteria

People over 18 years old in the chronic phase after experiencing a supratentorial unilateral stroke (> 6 months ago) that resulted in a hemiparesis. Furthermore, healthy controls of similar age and young healthy controls (18-30 years) will be included.

Exclusion criteria

With regard to the tDCS measurements:

- Neurological or orthopedic conditions affecting balance.

- Medication negatively affecting balance or reaction times.

- Disorders of hearing, which cannot be corrected to normal.

- Severe vision problems.

- Severe cognitive impairments.

- Serious head trauma or brain surgery.

- 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.

- Participated in a TMS or tCS study less than 1 year ago.

Additional criteria with regard to MRI measurement:

- Suffering from claustrophobia

- Suffering from epilepsy

- Cochlear implant

- Irremovable piercing or medical patch

- Any head, neck or shoulder surgeries in the past.

- BMI > 35

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo

Recruitment

NL

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

Enrollment:	45
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	13-04-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 42035
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5684
NTR-old	NTR5828
CCMO	NL51735.091.15
OMON	NL-OMON42035

Study results

Summary results
N/A