Effect van hersenstimulatie op de benen.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29069

Source
NTR

Brief title
NOLOMOCO

Health condition

Stroke

Sponsors and support

Primary sponsor: University of Twente
Source(s) of monetary or material Support: ZonMW

Intervention

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 and the motricity index.

Study description

Background summary

N/A

Study objective

Dual-hemisphere transcranial Direct Current Stimulation (tDCS) will result in a larger increase of the corticomotor excitability than uni-hemispere tDCS in healthy subjects and chronic stroke survivors.

Study design

N/A

Intervention

tDCS will be applied over the leg motor cortex of the subjects in 3 sessions. 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.

Contacts

Public
Postbus 217
Edwin Asseldonk, van
Enschede 7500 AE
The Netherlands
+31 (0)53 4892446
Scientific
Postbus 217
Edwin Asseldonk, van

Enschede 7500 AE
The Netherlands
+31 (0)53 4892446

Eligibility criteria

Inclusion criteria

The inclusion criteria for the healthy subjects are:

1. Age > 18 years;

2. Able to walk on a treadmill.

The inclusion criteria for the stroke survivors are:

1. Age > 18 years;

2. Diagnosed with a hemiparesis as the result of a first ever, ischemic stroke;

3. Chronic stage: Time since stroke > 6 months;

4. Independent (score 4 to 5 on the functional ambulation classification) walkers with a clear walking impairment (asymmetry, reduced knee flexion during swing);

5. A stable medical condition;

6. A physical condition which allows for 3 minutes of walking;

7. Sufficient cognitive abilities (Mini-Mental State Examination ≥ 22);

8. Sufficient communication abilities (Utrechtse Communicatie Onderzoek ≥ 3).

Exclusion criteria

1. History of cardiac arrhythmias;

2. History of skin diseases that could result in irritation of the head skin underneath the electrodes;

3. Metallic implants in the brain;

4. Presence of cardiac pacemakers, cochlear implant or implanted brain electrodes;

5. Unexplained head aches;

6. Use medications that form a relative hazard for application of TMS due to a seizure threshold lowering potential;

7. Use medications that alters the cortical excitability;

8. (Possibility) of pregnancy;

9. Used any illegal drugs in the last month;

10. Had spinal surgery, or have drains in their spinal cord or ventricles;

11. Current orthopedic problems;

12. Other neurological disorders;

13. Chronic joint pain;

14. A history of cardiac conditions that interfere with physical load;

15. Severe depression.

Study design

Design

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

Recruitment

NL
Recruitment status: Pending

Start date (anticipated):	15-02-2011
Enrollment:	20
Type:	Anticipated

Ethics review

Not applicable
Application type: Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 38314
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL2601
NTR-old	NTR2729
CCMO	NL34235.044.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON38314

Study results

Summary results
N/A