Brain-STimulation for Arm Recovery after Stroke

Published: 19-10-2016
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To determine the therapeutic effect of contralesional cTBS on recovery of function of the paretic arm, at 3 months after ischemic stroke

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Embolism and thrombosis
Study type	Interventional

Summary

ID

NL-OMON50466

Source
ToetsingOnline

Brief title
B-STARS

Condition

- Embolism and thrombosis

Synonym
cerebrovascular accident, Stroke

Research involving
Human

Sponsors and support

Primary sponsor: Divisie Beeld
Source(s) of monetary or material Support: Netherlands Organisation for Scientific Research/Netherlands Organisation for Health Research and Development. ZonMw/NWO

Intervention

Keyword: Brain stimulation, Recovery, Rehabilitation, Stroke

Outcome measures

Primary outcome

Performance on an upper limb function test of the paretic arm.

Secondary outcome

Performance on additional upper limb function tests, tests on disability and

quality of life and neural network reorganisation. Optional are the MRI scans

and a single interview.

Study description

Background summary

Many surviving stroke patients are left with moderate to severe functional deficits and long-term dependency on rehabilitation services. The most common functional deficits after stroke are sensorimotor impairments, especially no or limited ability to execute muscle movements with the affected arm or hand.1-2 Hemiparetic stroke recovery is often associated with an imbalanced interaction between the damaged and undamaged hemispheres, with reduced excitability of the ipsilesional primary motor cortex (M1) while excitability in the contralesional M1 is increased.19-25 Theta Burst Stimulation (TBS), one of many forms of rTMS, can elicit significant behavioral improvement in recovering stroke patients.26-28 Despite these promising findings, a randomized controlled trial (RCT) on the long term effects of TBS treatment in subacute, hemiparetic stroke patients is lacking.35-37 We hypothesize that in stroke patients who receive TBS the upper limb motor recovery is more pronounced (faster with higher motor scores) in contrast to patients receiving sham TBS.

Study objective

To determine the therapeutic effect of contralesional cTBS on recovery of function of the paretic arm, at 3 months after ischemic stroke

Study design

A double-blind randomized placebo-controlled intervention study. Patients will be randomly assigned to one of two groups: one group of patients will receive cTBS stimulation and the other group will receive sham stimulation. Both groups will receive stimulation (followed by standard care upper limb training) for 10 days, during 2 weeks, and will be tested 7 times (in total). Optional are the MRI scans and a single interview.

Intervention

Contralesional cTBS over the hand area of the primary motor cortex on a daily basis for 2 weeks (except the weekends). Sham stimulation will be done with a reverse coil orientation.

Study burden and risks

TBS is relatively well-tolerated in the adult and child population according to several systematic reviews. Generally, it is a safe technique, especially when safety guidelines are followed.58-61 The burden will consist of daily stimulation sessions, lasting 40 seconds, (during two weeks) and multiple outcome measurements (at baseline and at 6 follow-up time-points). This is extensive, but the research can only be performed with these patient groups.

Contacts

Public
Selecteer

Heidelberglaan 100
Utrecht 3584CX
NL
Scientific
Selecteer

Heidelberglaan 100
Utrecht 3584CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1) Adult patient age * 18;
2) first-ever unilateral ischemic and hemorrhagic stroke (i.e., within the cerebral hemispheres, brainstem);
3) paresis of one arm, with a SA score shoulder abduction *9 (Motricity Index);
4) within the first 3 weeks after stroke onset;
5) signed informed consent.

Exclusion criteria

1) Disabling medical history (severe or recent heart disease, severe head trauma, coercively treated at a psychiatric ward);
2) history of epilepsy;
3) Normal to almost normal use of hand; maximum Motricity Index hand score (score of 33)
4) severe deficits in communication, memory, or understanding that impede proper study participation, as determined by the treating physician;
5) contraindications for TMS (e.g. metal (implants) in skull/scalp/head or fragments from welding or metalwork, implanted device, pregnancy). N.B. metal fillings (i.e. conductive) or non-ferromagnetic dental implants are an exception to the rule.

Study design

Design

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

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-04-2017
Enrollment:	60
Type:	Actual

Medical products/devices used

Generic name:	Magnetic brain stimulator
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	19-10-2016
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	15-03-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	17-05-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	28-12-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	12-09-2018
Application type:	Amendment
Review commission:	METC NedMec

Approved WMO Date:	13-03-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	06-11-2020
Application type:	Amendment
Review commission:	METC NedMec

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: 19906
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL58423.041.16
OMON	NL-OMON19906

Study results

Date completed:	26-01-2022
Actual enrolment:	60