Brain STimulation for Arm Recovery after Stroke 2

Published: 31-05-2024
Last updated: 04-04-2025

To assess whether 10 sessions of cTBS of the contralesional primary motor cortex combined with regular care upper limb training, started within three weeks after stroke onset, are effective and cost effective in promoting upper limb recovery after...

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

Summary

ID

NL-OMON56798

Source
ToetsingOnline

Brief title
B-STARS2

Condition

- Central nervous system vascular disorders

Synonym
Stroke;

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum
Source(s) of monetary or material Support: Zorginstituut Nederland

Intervention

Keyword: Recovery, Rehabilitation, rTMS, Stroke

Outcome measures

Primary outcome

The upper extremity section of the Fugl-Meyer assessment (FM-UE) at 90 days post-stroke.

Secondary outcome

The FM-UE at 12 months post-stroke.

The Action Research Arm Test (ARAT) at 90 days and 12 months post-stroke.

Activities of daily living (ADL), memory, handfunction and participation sections of the Stroke Impact Scale (SIS) at 90 days and 12 months post-stroke.

Nine Hole Peg Test at 90 days and 12 months post-stroke.

modified Rankin Scale at 90 days and 12 months post-stroke.

EuroQol-5D at 90 days and 6 and 12 months post-stroke.

iMTA medical consumption and productivity cost questionnaire

Length of stay

Ipsilesional excitability after the 10th cTBS session (optional)

Contralesional excitability before the 1st, 6th and 10th cTBS session

TMS disruption at baseline

Study description

Background summary

Every year, about 40,000 people in the Netherlands have a stroke. After the initial admission to the hospital, about 15% of stroke survivors is admitted to

a rehabilitation center. These patients are younger (average age of about 60 years) than those discharged to a chronic nursing facility and have more severe motor impairments than those discharged home. About 75% of these patients has upper limb dysfunction, which significantly hampers activities of daily living. Upper limb function plays a critical role in the performance of all daily life activities (like eating, taking a shower, using a computer, riding a bike, etc.). Most everyday activities require the use of both hands. Improved arm and hand function positively contributes to societal participation and quality of life. Incomplete upper limb recovery has been found to be the strongest predictor of lower health-related quality of life, across almost all quality-of-life domains (except mobility), even after correcting for stroke characteristics. Moreover, stroke survivors with a high score on a life satisfaction scale reported better manual ability.
Data from our phase-2 trial (B-STARS) indicate that continuous theta burst stimulation (cTBS) treatment, a form of repetitive transcranial magnetic stimulation (rTMS) results in 17% additional recovery of upper limb function, as measured with the ARAT score three months after stroke. This improvement exceeds the minimal clinically important difference of 10%. This additional recovery led to a significant improvement in the activity and participation domain (of similar magnitude) and a reduction in the length of stay at the rehabilitation center by 18 days on average.

Study objective

To assess whether 10 sessions of cTBS of the contralesional primary motor cortex combined with regular care upper limb training, started within three weeks after stroke onset, are effective and cost effective in promoting upper limb recovery after stroke, compared to sham stimulation.

Study design

A multi-center double-blind randomized sham(placebo)-controlled clinical trial.

Intervention

10 daily sessions of cTBS delivered over the contralesional primary motor cortex during a period of 2 weeks, delivered before regular care physical therapy of the affected upper limb.

Study burden and risks

Data from our phase-2 trial (B-STARS) indicate that cTBS treatment results in 17% additional recovery of upper limb function, as measured with the ARAT score three months after stroke. This improvement exceeds the minimal clinically important difference of 10%. This additional recovery led to a significant improvement in the activity and participation domain (of similar

magnitude) and a reduction in the length of stay at the rehabilitation center by 18 days on average.
Risks associated with participation were limited. Side effects in the active group were limited to headache (<4%) and muscle pain (<1%). The risk of inducing an epileptic seizure is very small (0.02%) and consequences of an epileptic seizure can be mitigated by adequate training of personnel. Participating in the optional TMS measurement at De Hoogstraat Rehabilitation has a negligible increase in the risk of TMS-related side effects.

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

Age, 18 years or older;
First-ever unilateral ischemic stroke or intracerebral hemorrhage in a cerebral

hemisphere or the brainstem;
Unilateral upper limb paresis with a motricity index between 9 and 99;
Possibility to start cTBS treatment within 21 days after stroke onset;
Signed informed consent.

Exclusion criteria

Upper limb paresis prior to stroke onset;
Magnetically sensitive objects implanted in or guided through the head or neck area (e.g. cochlear implants, implanted neurostimulator, pacemaker or defibrillator leads, metal splinters, metal fragments or metal clips) with the exception of dental work (e.g. fillings, braces or implants), history of epilepsy, pregnancy or other contra-indications that may potentially be harmful as determined by the treating rehabilitation physician;
Incapacity or severe impairments (i.e. extreme fatigue, major communication deficits) that can impede study participation as determined by the treating rehabilitation physician;
Life expectancy shorter than one year.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-12-2024
Enrollment:	454
Type:	Actual

Medical products/devices used

Generic name:	Transcranial magnetic stimulator
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	31-05-2024
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	01-08-2024
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	20-11-2024
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	28-02-2025
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

No registrations found.

In other registers

Register	ID
CCMO	NL85511.041.24