

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Evaluation of the effect of adding direct transcranial stimulation (tDCS) of Dorsolateral Prefrontal Cortex to primary motor cortex on spasticity and improvement of upper limb motor function in patients with chronic stroke: A double-blind controlled clinical trial

Protocol summary

Study aim

Evaluation of the effect of adding direct transcranial stimulation (tDCS) of Dorsolateral Prefrontal Cortex to primary motor cortex on spasticity and improvement of upper limb motor function in patients with chronic stroke

Design

A clinical trial with a double-blind randomized control group on 42 patients, using Randomization site for randomization.

Settings and conduct

By referring to the hospitals of Rasht city, after examining the patients with stroke, the neurologist will provide the necessary explanations about the study objectives and the method of its implementation for the people who meet the entry criteria. Then, if they agree to participate. Consciously and voluntarily in the research, they sign the consent form. After obtaining informed consent, the questionnaire of personal information and disease will be completed and then the cognitive status will be done with MMSE test. Then, in order to measure the severity of spasticity of patients' flexor wrist muscles and functional status, the Persian version of the MMAS and FM test will be used, respectively. Evaluations are performed after the first and last (fifth) session of electrical stimulation.

Participants/Inclusion and exclusion criteria

Patients with chronic ischemic stroke who have been injured for at least six months are included in the study. The severity of spasticity 1 and higher and the ability to understand and communicate verbally are other conditions for inclusion in the study. If the patient is allergic to cranial stimulation or does not want to cooperate, will be excluded from the study.

Intervention groups

Intervention group: real stimulation of the primary motor area and Dorsolateral prefrontal cortex. Control group:

real stimulation of the primary motor area and sham stimulation of Dorsolateral prefrontal cortex.

Main outcome variables

Motor function, spasticity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211030052912N1**

Registration date: **2021-11-11, 1400/08/20**

Registration timing: **prospective**

Last update: **2021-11-11, 1400/08/20**

Update count: **0**

Registration date

2021-11-11, 1400/08/20

Registrant information

Name

Somaye Azarnia

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 7173 2824

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-19, 1400/09/28

Expected recruitment end date

2022-05-10, 1401/02/20 Actual recruitment start date empty Actual recruitment end date empty Trial completion date empty	According to the two intervention groups (A) and control (B), six Quadruple blocks will be used in this method. Each sequence is then recorded on a card and placed in an envelope. In order of patients' arrival, the envelopes are opened and the assigned group of the participant is determined.
Scientific title Evaluation of the effect of adding direct transcranial stimulation (tDCS) of Dorsolateral Prefrontal Cortex to primary motor cortex on spasticity and improvement of upper limb motor function in patients with chronic stroke: A double-blind controlled clinical trial Public title Evaluation of the effect of adding direct transcranial stimulation (tDCS) of Dorsolateral Prefrontal Cortex to primary motor cortex on spasticity and improvement of upper limb motor function in patients with chronic stroke: A double-blind controlled clinical trial	Blinding (investigator's opinion) Double blinded Blinding description In this double-blind study, patients and evaluators are unaware of the type of group assigned. Randomization and intervention will be performed by a person who is not involved in the patient evaluation process and the evaluator is unaware of the type of intervention. Placebo Used Assignment Parallel Other design features
Purpose Treatment Inclusion/Exclusion criteria Inclusion criteria: First ischemic stroke صافرا At least 6 months have passed since the stroke MCA stroke Patients using the ashworth Modified Modified Scale (MMAS) to have a wrist flexion muscle spasm severity of 1 or higher Patients without chronic neurological diseases such as Parkinson's, Alzheimer's, schizophrenia, radiculopathy, and musculoskeletal disorders, especially upper extremity movement disorders, diagnosed by a neurologist Ability to communicate verbally with the therapist Do not take drugs that change a person's cognitive status No heart disease and pacemaker, No history of seizures, previous brain surgery Patients without severe cognitive and memory impairment. To determine this, the Persian version of MMSE is used and patients must obtain a minimum score of 23 out of a total of 30 points. Exclusion criteria: Hemorrhagic stroke patients Stroke patients with arterial injury other than the middle cerebral artery Patients with lacunar stroke Patients with acute and subacute ischemic stroke	Secondary Ids empty Ethics committees <u>1</u> Ethics committee Name of ethics committee Ethics Committee of the University of Rehabilitation Sciences and Social Health Street address Evin City Tehran Province Tehran Postal code 1985713834 Approval date 2021-10-20, 1400/07/28 Ethics committee reference number IR.USWR.REC.1400.185
Age No age limit Gender Both Phase N/A Groups that have been masked - Participant - Outcome assessor	Health conditions studied <u>1</u> Description of health condition studied Stroke ICD-10 code I67 ICD-10 code description Other cerebrovascular diseases
Sample size Target sample size: 42 Randomization (investigator's opinion) Randomized Randomization description Randomization will be done through Randomization.com.	Primary outcomes <u>1</u> Description Motor function

Timepoint

Upon entering the study, after the first and last session of stimulation

Method of measurement

Fugl meyer test

2

Description

Spasticity

Timepoint

Upon entering the study, after the first and last session of stimulation

Method of measurement

Modified Modified Ashworth Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Anodal stimulation of the M1 and pDLPFC of the involved side. To create electrical brain movements, 2 devices of a tDCS channel, model Activados, made in the USA will be used. Active electrodes according to the involved side, is left M1(c3) and DLPFC(F3) or right m1 (c4) and DLPFC (F4) and reference electrodes will be placed on the contralateral of superorbital . Constant current with an intensity of 1 mA for 20 minutes with active electrode of 16 cm2 and a reference electrode of 35 cm2 will be used.

Category

Rehabilitation

2

Description

Control group: Real anodal stimulation of the primary motor cortex and sham stimulation of the Dorsolateral prefrontal cortex involved side. To create electrical stimulation of the brain, two single-channel devices tDCS model Activados made in the United States will be used. Active electrodes according to the involved side, is left M1(c3) and DLPFC(F3) or right m1 (c4) and DLPFC (F4) and reference electrodes will be placed on the superorbital of contralateral side. A constant current of 1 mA is applied to the M1 region for 20 minutes. Stimulation in theDorsolateral prefrontal cortex is extinguished with the same intensity after 30 seconds. In order to localize the excitability of the motor cortex, an active electrode of 16 cm2 and a reference electrode of 35 cm2 will be used.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Porsina hospital

Full name of responsible person

Somaye Azarnia

Street address

Namjoo

City

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Province

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Somaye Azarnia

Street address

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

University of social welfare and rehabilitation sciences

Proportion provided by this source

70

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

azarnia.pt.82@gmail.com

Contact

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Somaye azarnia

Position

Student

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

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University of social welfare and rehabilitation sciences

Full name of responsible person

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Data confidentiality

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available