Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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

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

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

First ischemic stroke Iصاهزا 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

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done through Randomization.com. According to the two intervention groups (A) and control (B), six Quadriple 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.

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

Secondary Ids

empty

Ethics committees

1

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

Health conditions studied

1

Description of health condition studied

Stroke

ICD-10 code

I67

ICD-10 code description

Other cerebrovascular diseases

Primary outcomes

1

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 Activodos 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
University of social welfare and rehabilitation sciences
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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

Contact

Name of organization / entity
University of social welfare and rehabilitation sciences
Full name of responsible person
Somaye azarnia
Position
Student
Latest degree
Master
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Person responsible for updating data

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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