Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluation of the effect of Unihemispheric Concurrent Dual-Site Transcranial Direct Current Stimulation of Dorsolateral Prefrontal Cortex AND primary motor cortex on improvement of lower limb motor function in patients with chronic stroke: A double-blind controlled clinical trial

Protocol summary

Study aim
Investigating the effect of unilateral tDCS stimulation of primary motor cortex and dorsolateral prefrontal cortex on the improvement of upper limb function in chronic stroke patients

Design
A clinical trial with a double-blind randomized control group

Settings and conduct
By referring to the neurological center, after examining the stroke patients by the neurologist, we will provide the necessary explanations about the study for the people who meet the entry criteria. Then, if they agree to participate, they sign the consent form. After obtaining informed consent, the questionnaire of personal information and disease will be completed and the cognitive status will be done with the Mini–Mental State Examination (MMSE) test. Then, to measure the severity of spasticity of patients' knee flexor muscles and functional status, the Persian version of the Modified Modified Ashworth Scale and Fugl Meyer test will be used, respectively. Evaluations are performed after the first and last (fifth) session of electrical stimulation.

Participants/Inclusion and exclusion criteria
Chronic ischemic stroke patients who have at least six months since their injury and have spasticity level 1 or higher are included in the study.

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

Main outcome variables
Motor function

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211030052912N3**
Registration date: **2023-01-28, 1401/11/08**
Registration timing: **retrospective**

Last update: **2023-01-28, 1401/11/08**
Update count: **0**

Registration date
2023-01-28, 1401/11/08

Registrant information

Name
Somaye Azarnia

Name of organization / entity

Country
Iran (Islamic Republic of)

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Email address
azarnia.pt.82@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-12-06, 1401/09/15

Expected recruitment end date
2023-01-10, 1401/10/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Evaluation of the effect of Unihemispheric Concurrent Dual-Site Transcranial Direct Current Stimulation of Dorsolateral Prefrontal Cortex AND primary motor cortex on improvement of lower limb motor function in patients with chronic stroke: A double-blind controlled clinical trial

Public title

Evaluation of the effect of Unihemispheric Concurrent Dual-Site Transcranial Direct Current Stimulation of Dorsolateral Prefrontal Cortex AND primary motor cortex on improvement of lower limb motor function in patients with chronic stroke: A double-blind controlled clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

First stroke Medial Cerebellar Artery (MCA) stroke The ability to verbally communicate with the therapist Patients using the Ashworth Modified Modified Scale (MMAS) to have a knee flexion muscle spasm severity of 1 or higher No history of a brain tumor Patients who do not have severe cognitive and memory disorders. To determine this, the Persian version of the Mini-Mental State Examination is used and patients must score at least 23 out of a total of 30

Exclusion criteria:

Patients with chronic neurological diseases such as Parkinson's, Alzheimer's, schizophrenia, radiculopathy, and musculoskeletal disorders, especially upper extremity movement disorders, diagnosed by a neurologist. History of seizures, previous brain surgery, heart disease and pacemaker Take drugs that change a person's cognitive status

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **37**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done through Randomization.com. In this method, according to the two intervention groups (A) and control (B), 6 blocks of 4 will be determined. 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. 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

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to protect patients 'personal information, patients' names and the type of study group are entered in a booklet along with a numeric code that has nothing to do with the national code or ID number, and all information in the computer and forms and analyzes are based on that numeric code. And the booklet will only be kept safe by the researcher and out of reach of others, and the information reported in the research will not be such that the identity of patients can be ascertained. At the beginning of the implementation, all patients are informed that they may be in the intervention or control group, but will be unaware of this issue until the end of the project. After extracting the data, if the intervention is effective, the control group will be called and effective intervention for them. In addition to the patients, the person analyzing the MRS results (evaluator) is also unaware. Randomization and intervention will be performed by a person who is not involved in the patient evaluation process.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the Guilan University of Medical Sciences

Street address

Namjoo avenue

City

Rasht

Province

Guilan

Postal code

13111-41937

Approval date

2022-11-09, 1401/08/18

Ethics committee reference number

ir.gums.rec.1401.408

Health conditions studied

1

Description of health condition studied

Stroke

ICD-10 code

G46

ICD-10 code description

Vascular syndromes of brain in cerebrovascular diseases

Primary outcomes

1

Description
Motor function
Timepoint
Before the first and after last electrical stimulation
Method of measurement
Fugl meyer test

2

Description
Brain metabolite activity,
Timepoint
Before the first and after last electrical stimulation
Method of measurement
Metabolite content with Magnetic resonance imaging

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Anodal stimulation of the M1 and DLPFC of the involved side. The two-channel device 2-NEUROSTIM manufactured by Medina Medical Company will be used to create electrical brain movements. The location of the electrodes will be determined using the international 10-20 system of electroencephalography. The location of the electrodes is determined using an international system of 10-20 electroencephalographs. The electrode pads are soaked in saline. 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.The electrical stimulation will last for 5 sessions. After stimulating the patient, he will perform routine upper extremity exercises.
Category
Rehabilitation

2

Description
Control group: real M1 anal stimulation and sham DLPFC on the involved side. To generate brain electrical stimulations, the 2-NEUROSTIM two-channel device manufactured by Medina Tabgaster Company will be used. The location of the electrodes is determined using the international 10-20 electroencephalography system . The electrode pad is soaked in physiological serum solution. Active electrodes according to the involved side in the areas of the primary motor cortex equivalent to c3 and the posterior-lateral prefrontal cortex equivalent to F3 (in the left involvement) or the primary motor cortex equivalent to c4 and the posterior-lateral prefrontal cortex equivalent to F4 (right involvement) and reference electrodes on They will be placed on the supraorbital of the uninvolved side. A constant current with an intensity of 1 milliampere is applied for 20 minutes in a real way on the c3/c4 area and as a sham on the F3/F4 area. In order to localize the excitability of the motor cortex, the active electrode of 16 cm2 and the reference electrode of 35 cm2 will be used. Electrical stimulation will be for 5 sessions.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Pars hospital.rasht
Full name of responsible person
Somaye Azarnia
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Pars Hospital, Shahid Gholipour Boulevard, Rasht, Iran
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2

Recruitment center
Name of recruitment center
Persepolis physiotherapy
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
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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
Rasht University of Medical Sciences

Proportion provided by this source
100

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
Rasht University of Medical Sciences
Full name of responsible person
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Position
Student
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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
Confidentiality of data

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