

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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)

##### Phone

+98 21 7173 2824

##### 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 cm<sup>2</sup> and a reference electrode of 35 cm<sup>2</sup> 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 milliamperere 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 cm<sup>2</sup> and the reference electrode of 35 cm<sup>2</sup> 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

##### Street address

Pars Hospital, Shahid Gholipour Boulevard, Rasht, Iran

##### City

Rasht

##### Province

Guilan

##### Postal code

4158813455

##### Phone

+98 13 3212 6173

##### Email

-info@pars-hospital.com

### 2

#### Recruitment center

##### Name of recruitment center

Persepolis physiotherapy

##### Full name of responsible person

Somaye Azarnia

##### Street address

Units 11 and 18, first floor,Dana doctors building, Golsar intersection, Rasht

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##### Province

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4188866449

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##### Email

ez\_kamran@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Rasht University of Medical Sciences

**Full name of responsible person**

Heydar Ali Balu

**Street address**

Guilan University of Medical Sciences' Headquarters,  
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riasat@gums.ac.ir

**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**

Somaye Azarnia

**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

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**Latest degree**

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**Other areas of specialty/work**

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**Person responsible for updating data****Contact****Name of organization / entity**

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PhD student

**Latest degree**

Master

**Other areas of specialty/work**

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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