Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The Effect of Unihemispheric Concurrent Dual-Site Transcranial Direct Current Stimulation of Primary Motor and Dorsolateral Prefrontal Cortices on cerebral plasticity (with magnetic resonance spectroscopy) in Patients With chronic Stroke: A double-blind controlled clinical trial

Protocol summary

Study aim
Evaluation of the effect of a-tDCSUHCDS (M1-DLPFC) treatment on neuroplasty in patients with chronic stroke.

Design
Clinical trial with a two-way blind randomized control group

Settings and conduct
By referring to Pars Hospital in Rasht, after examining patients with stroke, a neurologist will provide the necessary explanations about the study objectives and its implementation method for people who have entry criteria, and if agreed, the consent form will be provided. They sign the letter. The candidate is assured that they can refuse to cooperate at any stage of the investigation and that all personal and medical information remains confidential. After obtaining informed consent, a comprehensive questionnaire containing personal information and illness will be completed and then the cognitive status will be assessed by MMSE test. Then, MRS participants will be taken to examine brain metabolites.

Participants/Inclusion and exclusion criteria
Stroke patients who have had a lesion for at least six months

Intervention groups
Intervention: Real stimulation of the primary motor area and the Dorsolateral prefrontal cortex Control: Real stimulation of the primary motor area and sham stimulation of the Dorsolateral prefrontal cortex

Main outcome variables
Brain metabolite activity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211030052912N2**
Registration date: **2021-11-13, 1400/08/22**
Registration timing: **prospective**

Last update: **2021-11-13, 1400/08/22**
Update count: **0**

Registration date
2021-11-13, 1400/08/22

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
2021-11-29, 1400/09/08

Expected recruitment end date
2022-04-22, 1401/02/02

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effect of Unihemispheric Concurrent Dual-Site

Transcranial Direct Current Stimulation of Primary Motor and Dorsolateral Prefrontal Cortices on cerebral plasticity (with magnetic resonance spectroscopy) in Patients With chronic Stroke: A double-blind controlled clinical trial

Public title

The Effect of Unihemispheric Concurrent Dual-Site Transcranial Direct Current Stimulation of Primary Motor and Dorsolateral Prefrontal Cortices on cerebral plasticity (with magnetic resonance spectroscopy) in Patients With chronic Stroke: A double-blind controlled clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

First ischemic stroke MCA stroke At least 6 months have passed since the stroke Patients with chronic neurological diseases such as Parkinson's, Alzheimer's, schizophrenia, radiculopathy, and musculoskeletal disorders, especially upper extremity movement disorders, are not diagnosed by a neurologist No history of brain tumor 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 with 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:

Lack of patient cooperation for post-intervention tests . People who withdraw from the research for any reason and do not want to continue the research. Severe fatigue so that the person is unable to continue the test Sensitivity of the patient's scalp to stimuluse

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **22**

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 University of Rehabilitation Sciences and Social Health

Street address

No. 10/1, Shahid Nazari St., Shahid Beheshti Blvd, Rasht

City

Rasht

Province

Guilan

Postal code

4145985715

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

G46

ICD-10 code description
Vascular syndromes of brain in cerebrovascular diseases

Primary outcomes

1

Description
Brain metabolite activity
Timepoint
Before and after the first electrical stimulation
Method of measurement
Metabolite content based on PPM with MRI

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. 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
Treatment - Other

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
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Pars hospital.rasht
Full name of responsible person
Somaye Azarnia
Street address
Evin
City
Tehran
Province
Tehran
Postal code
1985713834
Phone
+98 21 7173 2000
Email
azarnia.pt.82@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
University of social welfare and rehabilitation sciences
Full name of responsible person
Hamid Reza Khorram Khorshid
Street address
Evin
City
Tehran
Province
Tehran
Postal code
1985713834
Phone
+98 21 7173 2000
Email
azarnia.pt.82@gmail.com
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
50
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

Other areas of specialty/work
Physiotherapy

Street address
Evin

City
Tehran

Province
Tehran

Postal code
1985713834

Phone
71732000

Email
azarnia.pt.82@gmail.com

Person responsible for scientific inquiries

Contact

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

Full name of responsible person
Azarnia Somaye

Position
PhD Student

Latest degree
Master

Other areas of specialty/work
Physiotherapy

Street address
No. 10/1, Shahid Nazari St., Shahid Beheshti Blvd., Rasht Blvd.

City
Rasht

Province
Guilan

Postal code
4145985715

Phone
+98 13 3362 1657

Email
azarnia.pt.82@gmail.com

Person responsible for updating data

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

Street address
Evin

City
Tehran

Province
Tehran

Postal code
1985713834

Phone
71732000

Email
azarnia.pt.82@gmail.com

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