Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of the combined Transcranial Direct Current Stimulation with Task- Oriented Training on Electroencephalographic Biomarkers and involved upper limb motor function in hemiparesis post stroke

Protocol summary

Study aim

To determine the effect of the combined Transcranial Direct Current Stimulation with Task-Oriented Training on Electroencephalographic Biomarkers and upper limb motor function in ischemic stroke patients

Design

This study is a 2-armed, double-blind Randomized Clinical Trial with one-to-one allocation in two groups (group one: Real tDCs combined with task-oriented Training and group two: Sham tDCs combined with task-oriented Training) where the outcome assessor is completely blinded to the type of applied tDCs current. Since in the two treatment groups, the method of electrode placement and the feeling of current for 30 seconds at the beginning and end of the period of connecting the device to the patient's head are similar, it seems that it will not be possible to distinguish the type of intervention group by the patients.

Settings and conduct

The intervention is performed at the patient's house. In this study, both the participants and the assessor are blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria include having a diagnosis of a first unilateral ischemic stroke that at least 6 months have passed since the attack, age between 18 and 80 years, and motor function level equal to or more than 4 in the affected upper extremity based on the Branstrom motor function recovery stages and having a score equal or more than 26 on the MoCA. Exclusion criteria include having moderate to severe depression, receiving botox in the previous 6 months, and having contractures in the wrist and fingers of the affected side.

Intervention groups

Participants in the intervention group will receive "Real tDCs with task-oriented Training" and in the control group, "Sham tDCs with task-oriented Training" for 5 weeks, 3 sessions per week.

Main outcome variables

EEG: Absolute and Relative power, mean frequeny

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140222016680N9**
Registration date: **2022-10-08, 1401/07/16**
Registration timing: **prospective**

Last update: **2022-10-08, 1401/07/16**
Update count: **0**

Registration date

2022-10-08, 1401/07/16

Registrant information

Name

Shohreh Noorizadeh Dehkordi

Name of organization / entity

Iran University of Medical Sciences, School of Rehabilitation Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-30, 1401/08/08

Expected recruitment end date

2023-04-30, 1402/02/10

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of the combined Transcranial Direct Current Stimulation with Task- Oriented Training on Electroencephalographic Biomarkers and involved upper limb motor function in hemiparesis post stroke

Public title
The effect of transcranial direct current stimulation on upper limb motor function in stroke patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having a first unilateral ischemic stroke as confirmed by the MRI or CT-Scan At least 6 months have passed since the unilateral stroke Having the ability to walk for at least 10 meter (with or without cane) Having motor dysfunction in upper limb with a degree of recovery equal or more than 4 according to the recovery stages of Brunnstrom Having a score equal or above 26 in the "Montreal Cognitive Assessment"
Exclusion criteria:
Having moderate to severe depression (a score of 19 or higher on the "Beck depression scale") Received Botox in the previous 6 months (to enter the study, patients must not have received Botox in the past six months) Having a contracture in the wrist and fingers of the affected side Having other neurological disorders such as Parkinson, Multiple Sclerosis and etc. Having a thalamic stroke or central pain syndrome (Dejerine Roussy Syndrome) Pain in the affected shoulder (having a score of less than 12 based on the Pain Assessment section of the "Fugle-Meyer assessment" of the upper extremity) Using drugs that affect the central nervous system Having pace maker or other stimulation or ferromagnetic implants Having a history of Seizures in the last two years and taking anticonvulsant drugs during one month before the enrollment in the current study Pregnancy unwillingness and lack of cooperation to continue the treatment Having serious and persistent skin complications or sleep and concentration disorders due to stimulation with tDCs Not completing the treatment period or occurrence of an accident that affects the motor function or brain activity
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **36**
Randomization (investigator's opinion)
Randomized
Randomization description
Random blocks (permuted block randomization) with four blocks will be used for randomization. According to the sample size of 36, 18 blocks will be generated using the online site (www.sealedenvelope.com). For concealment in the randomization process, a unique code will be used on each envelope with the type of training specified inside. Stratification will be used in order to have the same distribution in terms of the affected side (right or left hemiplegia) in two groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, Assessor who evaluates the outcome measures of the survey will be blind to the allocation of the two treatment groups. Aditionally the data also will be assessed by a person who is blind to the type of treatment and treatment of groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic committee of Iran University of Medical Sciences
Street address
Iran University of Medical Sciences, Hemmat Expressway
City
Tehran
Province
Tehran
Postal code
Approval date
2022-02-23, 1400/12/04
Ethics committee reference number
IR.IUMS.REC.1400.1122

Health conditions studied

1

Description of health condition studied
unilateral ischemic stroke
ICD-10 code
163.9
ICD-10 code description
Cerebral infarction, unspecified

Primary outcomes

1

Description
Electroencephalography parameters include "Absolute power" and "Relative power" and "Average frequency" within each frequency subband (delta, theta, alpha, beta and gamma)
Timepoint
before treatment, after treatment (15th session), and 3 months later
Method of measurement
EEG recording

Secondary outcomes

1

Description
Upper limb motor function ability by the "Wolf Motor Function Test"
Timepoint
before treatment, after treatment (15th session), and 3 months later
Method of measurement
"Wolf Motor Function Test"

2

Description
upper limb motor function by the upper extremity part of the "Fugl-Meyer Assessment".
Timepoint
before treatment, after treatment (15th session), and 3 months later
Method of measurement
Upper Extremity part of the "Fugl-Meyer Assessment"

3

Description
patient's ability to handle objects of different sizes, weights and shapes
Timepoint
before treatment, after treatment (15th session), and 3 months later
Method of measurement
"Action Research Arm Test"

Intervention groups

1

Description
Intervention group: In this group, transcranial Direct Current Stimulation (tDCs) along with Task-Oriented Training are given for three weeks, 5 sessions per week, and each session for 60 minutes (15 sessions in total). Real-tDCs will be delivered by an anode electrode on the affected hemisphere. Real tDCS lasted 20 min at 2 mA, with a 30s ramp up and 30s ramp down. The exercises include 15 task-oriented exercises focusing on active and active-assistive movements to increase the range of motion of the upper limbs, grasping skills, grasping and moving, and releasing objects. Required equipment, tDCs device, and training supplies include a table, chair, ball, stacking checkers, and playing cards.
Category
Rehabilitation

2

Description
Control group: In this group, transcranial Direct Current Stimulation (tDCs) along with task-oriented exercises are given for three weeks, 5 sessions per week, and each session for 60 minutes (15 sessions in total). Sham tDCs will be delivered by the anode electrode on the affected hemisphere for 20 minutes. Sham tDCS consists of a 30-s ramp up followed by a 30-s ramp down of the current and between these intervals, the intensity of the current will be zero. The exercises include 15 task-oriented exercises focusing on active and active-assistive movements to increase the range of motion of the upper limbs, grasping skills, grasping and moving, and releasing objects. Required equipment, tDCs device, and training supplies include tables, chairs, balls, backgammon pieces, and playing cards.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Neurological physiotherapy Clinic, School of Rehabilitation Sciences, Iran University of Medical sci
Full name of responsible person
Shohreh Noorizadeh Dehkordi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity

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Full name of responsible person
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Grant name
Vice Cancellor for Research of Iran University of Medical Sciences

Grant code / Reference number

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

Title of funding source
Iran 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
Iran University of Medical Sciences

Full name of responsible person
Shohreh Noorizadeh Dehkordi

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
neurological rehabilitation

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

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