

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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 frequency

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

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Name of organization / entity

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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

AgeFrom **18 years** old to **80 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample sizeTarget 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. Additionally 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

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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

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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

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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