Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jul 2026

Double point versus single point stimulation in motor rehabilitation of paretic arms among stroke patients using transcranial direct current stimulation

Protocol summary

Summary

Objectives: Study purpose is determination of efficacy of brain stimulation with Transcranial Direct Current Stimulation(tDCS) in motor recovery of paretic upper extremities among acute ischemic stroke patients. Design: Study population will be acute ischemic stroke patients referred to Shariati hospital in Iran. The study will be a randomized double blind clinical trial with 30 patients in each arm. Ştratified randomization will be used for treatment allocation. Setting and conduct: After signing consents, patients will receive real or sham brain stimulation through a direct current stimulator. Patients visits will be done at baseline, and after two weeks, 4 weeks, and three months. Participants: Participants will be acute ischemic stroke patients referred to Shariati hospital in Tehran. Major exclusion criteria will be severe global aphasia due to stroke or dementia before or due to stroke. Intervention: Intervention arm patients will receive 5 sessions of real stimulation bihemispherically over the primary motor cortices, 30 minutes in duration and over 5 consecutive days, and another 30 minutes of real stimulation over the left dosrolateral prefrontal cortex. Sham group will receive sham stimulation over the both mentioned brain cortices for 5 sessions with 30 minutes duration at each stimulation site. Primary outcome measure will be measurement of upper extremity motor (measured by Fugl_Meyer test) and dexterity(measured by Action Research Arm test) abilities.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015102817867N3**
Registration date: **2017-06-10, 1396/03/20**
Registration timing: **prospective**
Last update:
Update count: **0**

Registration date

2017-06-10, 1396/03/20

Registrant information

Name

Shahram Oveisgharan

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8889 6696

Email address

oveis@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2017-06-22, 1396/04/01

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Double point versus single point stimulation in motor rehabilitation of paretic arms among stroke patients using transcranial direct current stimulation

Public title

Double stimulation versus single stimulation in

rehabilitation of stroke patients using transcranial direct current stimulation

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion Criteria: Stroke patients whose symptoms start within the last 4 days; stroke patients who suffer from upper extremity paresis due to stroke. Exclusion criteria: stroke patients with decreased level of consciousness; patients with metal foreign bodies in their heads; patients who do not sign the consent forms; patients who can not come regularly for three months after their first visit;patients with dementia before current stroke; patients who develop severe global aphasia or dementia after stroke.

Age
From **20 years** old to **90 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tehran University of Medical Sciences

Street address
Keshavarz Blvd

City
Tehran

Postal code

Approval date
2017-02-04, 1395/11/16

Ethics committee reference number
IR.TUMS.VCR.REC.1395.1618

Health conditions studied

1

Description of health condition studied
Ischemic Stroke

ICD-10 code
I63

ICD-10 code description
Cerebral Infarction

Primary outcomes

1

Description
Upper extremity motor capacity

Timepoint
Before intervention, week 2, month 1, month 3

Method of measurement
Fugl-Meyer test

2

Description
Upper extremity dexterity

Timepoint
Before intervention, week 2, month 1, month 3

Method of measurement
Action Research Arm Test

Secondary outcomes

1

Description
Disability in the daily activities

Timepoint
Before intervention, week 2, month 1, month 3

Method of measurement
Modified Rankin Scale

Intervention groups

1

Description
Intervention group: Brain stimulation will be done through a battery-driven constant current stimulator. Each patient's brain will be stimulated in five sessions in five consecutive days for about an hour per session. In the first 30 minutes, primary motor cortex will receive real stimulation. Anode electrode will be placed over the injured hemisphere and cathode electrode will be put over the intact hemisphere. In the 10/20 EEG system, primary motor cortex is compatible with C3/C4 points. In the second 30 minutes of stimulation, each patient's dorsolateral prefrontal cortex will be stimulated. Anode electrode will be placed over the left dorsolateral prefrontal cortex and cathode electrodes will be put just above the right mid-orbital area. In the 10/20 EEG system, left dorsolateral prefrontal cortex is compatible with F3 point. In both sessions, real stimulation will rise from zero to two milliamperes in 30 seconds, continue at

two milliamperes for 30 minutes, and decline from two to zero milliamperes in 30 seconds.

Category

Rehabilitation

2

Description

Control group: Brain stimulation will be done through a battery-driven constant current stimulator. Each patient's brain will be stimulated in five sessions in five consecutive days for about an hour per session. In the first 30 minutes, primary motor cortex will receive shaml stimulation. Anode electrode will be placed over the injured hemisphere and cathode electrode will be put over the intact hemisphere. In the 10/20 EEG system, primary motor cortex is compatible with C3/C4 points. In the second 30 minutes of stimulation, each patient's dorsolateral prefrontal cortex will receive sham stimulation. Anode electrode will be placed over the left dorsolateral prefrontal cortex and cathode electrodes will be put just above the right mid-orbital area. In the 10/20 EEG system, left dorsolateral prefrontal cortex is compatible with F3 point. In both sessions, stimulation will rise from zero to two milliamperes in 30 seconds, continue at zero milliamperes for 30 minutes, and decline from two to zero milliamperes in 30 seconds.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati Hospital

Full name of responsible person

Shahram Oveisgharan

Street address

Kargar St;

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences -

Full name of responsible person

Dr. Masud Yunesian

Street address

Chamran Blvd

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Sciences -

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shariati hospital Tehran University of Medical Sciences

Full name of responsible person

Shahram Oveisgharan

Position

Assistant Professor of Neurology

Other areas of specialty/work

Street address

North Kargar St

City

Tehran

Postal code

Phone

+98 21 8490 2224

Fax

Email

shogh2@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shariati hospital Tehran University of Medical Sciences

Full name of responsible person

Shahram Oveisgharan

Position

Assistant Professor of Neurology

Other areas of specialty/work

Street address

North Kargar St

City

Tehran

Postal code

Phone

+98 21 8490 2224

Fax

Email

shahram.oveisgharan@rush.edu

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Shariati hospital Tehran University of Medical Sciences

Full name of responsible person
Shahram Oveisgharan

Position
Assistant Professor of Neurology

Other areas of specialty/work

Street address
North Kargar St

City
Tehran

Postal code

Phone
+98 21 8490 2224

Fax

Email
shogh2@yahoo.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty