

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of transcranial direct current stimulation (tDCS) on the lower limb function with and without Step exercise in chronic stroke patients

Protocol summary

Study aim

The purpose of this study is to compare the effects of transcranial direct current stimulation (tDCS) on the lower limb function with & without Step exercise in chronic stroke patients.

Design

Randomized control clinical trial, with parallel groups, blinded subjects, with 30 sample size

Settings and conduct

This study will be performed in Neuromuscular Rehabilitation Research Center in Semnan. In the first group, direct current stimulation is delivered for 20 minutes on the brain motor cortex. In the second group, Step exercise will be performed, after this exercise, direct current stimulation is delivered on the brain motor cortex. In the control group, direct current stimulation is delivered on the brain motor cortex as a placebo. Subjects are blinded in this study, and they do the Timed Up and Go test with different foot positions before and after intervention randomly.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients should be able to stand and sit independently on a standard seat, and patients should be in the chronic stage. Exclusion criteria: Medical condition (apart from the stroke) that impair patients balance.

Intervention groups

Intervention group 1: Direct current stimulation is delivered 2 milliamperes (mA) for 20 minutes on the brain motor cortex in one session. Intervention group 2: Step exercise will be performed with the unaffected foot placed on a step and the affected foot placed at ground and subjects will do sit to stand task in this position for 30 minutes. After this exercise direct current stimulation is delivered 2 mA for 20 minutes on the motor cortex. Control group: Direct current stimulation is delivered for 20 minutes on the motor cortex as a placebo, and subjects perceived sensations on the skin, such as tingling, fade usually out in the first 30 seconds of direct

current.

Main outcome variables

The time of Timed Up and Go test

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160424027562N8**

Registration date: **2019-01-25, 1397/11/05**

Registration timing: **prospective**

Last update: **2019-01-25, 1397/11/05**

Update count: **0**

Registration date

2019-01-25, 1397/11/05

Registrant information

Name

Roghayeh Mohammadi

Name of organization / entity

Semnan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 23 3365 4180

Email address

mohammadpt@semums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-26, 1397/11/06

Expected recruitment end date

2019-06-20, 1398/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of transcranial direct current stimulation (tDCS) on the lower limb function with and without Step exercise in chronic stroke patients

Public title

Effect of transcranial direct current stimulation (tDCS) in chronic stroke patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

All patients should be able to stand and sit independently on a standard seat All the patients should be more than 6 months poststroke The spasticity score of plantarflexor muscles should be smaller than 3 in the modified Ashworth scale Stroke patients should be in the chronic stage

Exclusion criteria:

Medical condition (apart from the stroke) that impair patients balance Cognition deficiency

Age

From **45 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization is done. Since the therapeutic method is three models, for the four-block blocks, twenty-four different modes are created and based on the random numbers generated by the computer, the blocks are placed. Allocation concealment will be performed by using random seals enclosed envelopes.

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants will be blind in this study. In spite of explaining to patients about the intervention adequately, they will not be aware of being in which group.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Semnan University of Medical Sciences

Street address

Semnan University of Medical Sciences, Basij Blvd, Semnan

City

Semnan

Province

Semnan

Postal code

3514799442

Approval date

2018-12-18, 1397/09/27

Ethics committee reference number

IR.SEMUMS.REC.1397.201

Health conditions studied**1****Description of health condition studied**

Stroke

ICD-10 code

I67.9

ICD-10 code description

Cerebrovascular disease, unspecified

Primary outcomes**1****Description**

The time of Timed Up and Go test

Timepoint

Before and immediately after intervention

Method of measurement

By chronometer

Secondary outcomes**1****Description**

Berg Balance Scale

Timepoint

Before and immediately after intervention

Method of measurement

Questionnaire

Intervention groups**1****Description**

Intervention group 1: Direct current stimulation is

delivered 2 milliamperes for 20 minutes on the brain motor cortex in one session. An active electrode is positioned over the primary motor cortex of the affected side and a returning electrode is located over the contralateral supraorbital area.

Category

Rehabilitation

2

Description

Intervention group 2: Step exercise will be performed with the unaffected foot placed on a step and the affected foot placed at ground level and subjects will do sit to stand task in this position for 30 minutes after this exercise direct current stimulation is delivered 2 milliamperes for 20 minutes on the brain motor cortex. An active electrode is positioned over the primary motor cortex of the affected side and a returning electrode is located over the contralateral supraorbital area.

Category

Rehabilitation

3

Description

Control group: Direct current stimulation is delivered for 20 minutes on the brain motor cortex as a placebo, and subjects perceived sensations on the skin, such as tingling, fade usually out in the first 30 seconds of direct current

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Neuromuscular Rehabilitation Research Center

Full name of responsible person

Roghayeh Mohammadi

Street address

Neuromuscular Rehabilitation Research Center, Ghods Blvd, Semnan, Iran

City

Semnan

Province

Semnan

Postal code

3519698375

Phone

+98 23 3332 8502

Email

mohamadipt@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Dr. Parviz Kokhaei

Street address

Semnan University of Medical Sciences, Basij Blvd, Semnan

City

Semnan

Province

Semnan

Postal code

3514799442

Phone

+98 23 3345 1336

Email

P_kokha@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Roghayeh Mohammadi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Rehabilitation Faculty, Semnan University of Medical Sciences, 5 Kilometer of Damghan Road, Semnan, Iran

City

Semnan

Province

Semnan

Postal code

3513138111

Phone

+98 23 3365 4180

Email

Person responsible for scientific inquiries

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Roghayeh Mohammadi

Position

Assistant Professor

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Person responsible for updating data

Contact

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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

Not applicable

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

Not applicable

Data Dictionary

Not applicable