Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Nov 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
mohammadipt@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

mohamadipt@gmail.com

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

Latest degree
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Person responsible for updating data

Contact

Name of organization / entity
Semnan University of Medical Sciences

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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