Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Efficacy of transcranial direct current stimulation(tDCS) on functional connectivity, motor learning and cognitive functions in ischemic stroke patients: Double blind randomized clinical trail

Protocol summary

Study aim

Efficacy of transcranial direct current stimulation on functional connectivity, motor learning and cognitive functions in ischemic stroke patients.

Design

The sample size was estimated using G power software with an effect size of 0.61 and an alpha value of 0.05 and 45 individuals. This number is consistent with what has been stated in research literature. A sample of 45 ischemic stroke patients was randomly assigned to the 15 ABC blocks of three ABCs randomly divided into three groups of 15 each.

Settings and conduct

The study will be conducted at Zanjan University of Medical Sciences. Also In this study, participants and data analyzer will not be aware of the randomization process.

Participants/Inclusion and exclusion criteria

inclusion criteria: 1- Having informed consent to participate in the study. 2- A chronic stroke patient (> 3 months) diagnosed by imaging. 3- Having at least 40 and up to 80 years. 4- Having spent at least 3 months since infarction. 5- Having a marked motor deficiency in the upper and lower extremities with cerebrovascular injury. exclusion criteria: 1- Suicidal thoughts or risks that could not maintain stable dose of medication. 2- Psychiatric disorder and drug use, history of head injury and epileptic seizures, Epilepsy and head injury and pregnancy 4- Having no use of tDCS or fMRI.

Intervention groups

The first group received real tDCS intervention, the second group received placebo tDCS intervention, and the third group received no intervention.

Main outcome variables

Functional connectivity, Motor Learning, Cognitive functions and Depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190927044895N1**
Registration date: **2019-10-28, 1398/08/06**
Registration timing: **registered_while_recruiting**

Last update: **2019-10-28, 1398/08/06**
Update count: **0**

Registration date

2019-10-28, 1398/08/06

Registrant information

Name

Ahmadreza Zakerian zadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 74 3333 0046

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-28, 1398/07/06

Expected recruitment end date

2019-12-19, 1398/09/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Efficacy of transcranial direct current stimulation(tDCS) on functional connectivity, motor learning and cognitive functions in ischemic stroke patients: Double blind randomized clinical trail

Public title
Efficacy of transcranial direct current stimulation(tDCS) on stroke

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Having informed consent to participate in the study. A chronic stroke patient (> 3 months) diagnosed by imaging. Having at least 40 and up to 80 years of age and right-handedness. Having spent at least 3 months since infarction. Having a marked motor deficiency in the upper and lower extremities with cerebrovascular injury. Having at least mild cognitive impairment based on measuring instruments. Having mild depression symptoms based on the hamilton depression rating scale.

Exclusion criteria:
1- Suicidal thoughts or risks that could not maintain stable dose of medication. Psychiatric disorder and drug use. Having a history of head injury and epileptic seizures, Epilepsy and head injury and pregnancy. Having no use of tDCS or fMRI.

Age
From **40 years** old to **80 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **45**

Randomization (investigator's opinion)
Randomized

Randomization description
Blocked randomization, individual, layered, statistical software. A sample of 45 ischemic stroke patients was randomly accessed through the Web at https://www.sealedenvelope.com, The 15 ABC triplicate blocks were assigned by the supervisor in three 15-person in three groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
1- Patients do not know in which intervention group ABC (real intervention, sham and control) are. 2- Data analysis is performed by medical imaging systems team. As they are not aware of the nature of the ABC groups. All data will be encoded.

Placebo
Used

Assignment
Parallel

Other design features
This clinical trial consists of three groups: real intervention, sham and control, double-blind and randomized.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Zanjan University of Medical Sciences

Street address
Azadi Square, Zanjan University of Medical Sciences

City
Zanjan

Province
Zanjan

Postal code
45156-13191

Approval date
2019-07-29, 1398/05/07

Ethics committee reference number
IR.ZUMS.REC.1398.208

Health conditions studied

1

Description of health condition studied
Ischemic Stroke

ICD-10 code
G46.4

ICD-10 code description
Cerebellar stroke syndrome

Primary outcomes

1

Description
Functional connectivity

Timepoint
Pre-test, Post-test

Method of measurement
Functional Magnetic Resonance Imaging

2

Description
Motor Learning

Timepoint
Pre-test, Post-test and follow up (one month after post-test)

Method of measurement
Fugl-Meyer Test

3

Description
Cognitive functions
Timepoint
Pre-test, Post-test and follow up (one month after post-test)
Method of measurement
Montreal Cognitive Assessment

Secondary outcomes

1

Description
Depression
Timepoint
Pre-test, Post-test and follow up (one month after post-test)
Method of measurement
Hamilton Depression Rating Scale

2

Description
Attention
Timepoint
Pre-test, Post-test and follow up (one month after post-test)
Method of measurement
Selective and Divided Attention Test

3

Description
Balance
Timepoint
Pre-test, Post-test and follow up (one month after post-test)
Method of measurement
Berg Balance Scale

Intervention groups

1

Description
Intervention group one: The real stimulation was 2.0 mA for 30 minutes in the primary motor cortex, then 30 minutes rest without intervention and at the end real stimulation was performed 2.0 mA for 30 minutes in the dorsolateral prefrontal cortex. The intervention consists of 12 therapeutic sessions per day.
Category
Rehabilitation

2

Description
Intervention group two: Sham stimulation 2 mA after 60 seconds is interrupted in the patient's primary motor cortex, then 30 minutes rest without intervention and finally sham stimulation 2 mA after 60 seconds in the dorsolateral prefrontal cortex of the patient. The intervention consists of 12 therapeutic sessions per day.
Category
Rehabilitation

3

Description
Control group: No intervention
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Education and treatment Center Of Valiasr Zanjan
Full name of responsible person
Mohsen Dadashi
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Zanjan - Above Valiasr Square - Hazrat Valiasr Training Center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
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Web page address
http://zums.ac.ir/index.php?slc_lang=en&sid=1
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zanjan 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
Zanjan University of Medical Sciences
Full name of responsible person
Mohsen Dadashi
Position
Assistant Professor
Latest degree
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Person responsible for updating data

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Web page address
http://zums.ac.ir/index.php?slc_lang=en&sid=1

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is 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

Title and more details about the data/document

All of information related to main outcome will be published.

When the data will become available and for how long

Start the access period from 2020

To whom data/document is available

Researchers and clinicians working in academic and scientific institutions

Under which criteria data/document could be used

Access to documents is possible to inform other researchers and clinicians. Access to documents is possible to work with the researcher.

From where data/document is obtainable

DR. Beheshti Hospital, Zanjan, Department of Clinical Psychology, Dr Mohsen Dadashi, Mobile: 0098 9127433559. Dr. Beheshti Hospital, Zanjan, Department of Clinical Psychology,Ahmadreza Zakerian Zadeh, Mobile: 0098 9177432214

What processes are involved for a request to access data/document

Documents will be shared only when the reason for the request is announced by phone or e-mail.Response time is seven days.

Comments