Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

The effect of Dual-site Transcranial Direct Current Stimulation and computer-based rehabilitation on cognitive outcome in ischemic stroke patients.

Protocol summary

Study aim
Effectiveness of dual transcranial direct current stimulation and rehabilitation with computer-based software on the improvement of cognitive disorders in ischemic stroke patients

Design
Clinical trial type study that has four intervention groups. The sample size is 60 patients. The design of the study is parallel and includes the control group and there will be 15 patients in each group. Blinding is a double-blind type and randomization of patients is done using a table of random numbers.

Settings and conduct
Male and female patients with ischemic stroke hospitalized in acute and sub-acute phases in the scu department in Imam Reza hospital in Tabriz. After evaluation of patients and diagnosis of cognitive impairment by MOCA test and CANTAB software and QEEG recording, one week after discharge, treatment interventions will be performed for four groups and the patients will be re-evaluated EEG will be recorded again. Blinding will be double- blind method.

Participants/Inclusion and exclusion criteria
M/F patients with unilateral ischemic stroke in acute and sub-acute phase, age range of 40 to 65 years, having minimum reading and writing literacy, having NIHSS score 15 or less and mRS score 3 or less, obtaining MOCA score(18-25), not having movement problems in the dominant hand, not having a history of previous strokes and seizures, not having vision and hearing problems and no aphasic patients

Intervention groups
Group1) Two-site or dual transcranial direct current stimulation Group2) Cognitive rehabilitation using rehacom software combined with artificial exercises tDCS Group3) Cognitive rehabilitation with rehacom software combined with two-site transcranial direct current stimulation Group4) control, receiver of routine therapeutic rehabilitation

Main outcome variables
MOCA test, BARTHEL test, QEEG indicators, CANTAB cognitive test scores

General information

Reason for update

Acronym
RISP

IRCT registration information
IRCT registration number: **IRCT20221224056915N1**
Registration date: **2023-07-21, 1402/04/30**
Registration timing: **registered_while_recruiting**

Last update: **2023-07-21, 1402/04/30**
Update count: **0**

Registration date
2023-07-21, 1402/04/30

Registrant information

Name
marjan erfani

Name of organization / entity

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Iran (Islamic Republic of)

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+98 41 3335 1284

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-05-26, 1402/03/05

Expected recruitment end date

2025-04-25, 1404/02/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Dual-site Transcranial Direct Current Stimulation and computer-based rehabilitation on cognitive outcome in ischemic stroke patients.

Public title

The effect of rehabilitation on cognitive outcome in ischemic stroke patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Male and female patients with ischemic stroke in acute or subacute phases 40-65 years old If possible, live in Tabriz city Minimum reading and writing literacy(at least 9 classes) Ability to speak at least one of the Turkish or Farsi languages Absence of movement problems in the dominant hand NIHSS score of 15 or less mRS score of 3 or less Score below 26 and at least 18 in the MOCA test Ischemic stroke involvement unilaterally in the course of the middle cerebral artery

Exclusion criteria:

Illiterate people Patients with brainstem involvement Patients with a history of previous stroke Patients outside the age range patients with neuropsychological disorders patients with visual or hearing impairments Having intracranial metal implants or skin injuries on the target tissue stimulation area Suffering from severe heart-pulmonary and liver diseases Patients with a history of seizures Pregnant patients Having movement or perception problems for computer training Aphasic patients

Age

From **40 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

A simple method is used for randomization and the randomization unit is an individual. The randomization tool includes a table of random numbers and a sealed envelope, so that the list that is created for randomization by the computer with the help of a table of random numbers will be done by someone who has no role in other parts of the research and also the list will remain confidential with the person and will not be revealed until the study is completed, and when the patients visit, the number assigned to each person will be in an invisible envelope.

Blinding (investigator's opinion)

Double blinded

Blinding description

The participants of the current study, which include stroke patients, as well as, the patients companions and health care workers and the people who are in charge of data analysis will not have any knowledge about the allocation of patients to the intervention groups and will be kept blind. But the main researcher, the person who performs all the interventions, will be in charge of evaluating the results and the safety committee and data monitoring will not be blinded.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics commitee of Tabriz University of Medical Science

Street address

Azadi St. Golgasht St. Admonistrative Bulding-Research Ethics Committee of Tabriz University of Medical Science

City

Tabriz

Province

East Azarbaijan

Postal code

1475651666

Approval date

2023-05-22, 1402/03/01

Ethics committee reference number

IR.TBZMED.REC.1402.159

Health conditions studied

1

Description of health condition studied

Ischemic stroke

ICD-10 code

G46.0

ICD-10 code description

Middle cerebral artery syndrome

Primary outcomes

1

Description
MOCA Cognitive test score
Timepoint
After the end of the evaluation and after the completion of the intervention
Method of measurement
Use of questionnaires

2

Description
CANTAB cognitive software scores
Timepoint
At the end of the evaluation phase and after the completion of the interventions
Method of measurement
Cognitive software

Secondary outcomes

1

Description
Changes in patients brain waves
Timepoint
During the hospitalization of patients
Method of measurement
QEEG Device

Intervention groups

1

Description
Applying transcranial dual-site electrical stimulation with direct current
Category
Rehabilitation

2

Description
Intervention group: Using rehacom cognitive software
Category
Rehabilitation

3

Description
Intervention group: Simultaneous application of dual-site transcranial direct current stimulation and rehacom cognitive software
Category
Rehabilitation

4

Description
Control group: This group does not receive any intervention
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Dr Mehdi- Farhoudi- student(Marjan Erfani)
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Sponsors / Funding sources

1

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Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
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Full name of responsible person
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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