Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

A Clinical trial to evaluate the efficacy of Transcranial Direct Current Stimulations (TDCS) on movement and cognitive functions in patients with subacute brain ischemic stroke

Protocol summary

Summary

The aim of this double-blind clinical trial study is to evaluate the efficacy of Transcranial Direct Current Stimulations (TDCS) on movement and cognitive functions in patients with subacute brain ischemic stroke. The target population will be 100 patients with subacute brain ischemic stroke who referred to the specialized clinic of Toloo in Rasht. Patients will be selected by a psychiatrist based on clinical interview. After signing the informed consent and considering inclusion and exclusion criteria, participants will enter the study by Convenience sampling. After sampling, the samples will be allocated to the control group, sham group and two intervention groups. The exclusion criteria will be defined by a history of epilepsy or patients unwillingness to participate in the study. Treatment will be carried out in fifteen sessions, four sessions per week, and a direct and continuous electrical stimulation to the brain cortex through electrodes for a maximum duration of thirty minutes. Treatment effectiveness will be assessed after 15 days, 1 month and 3 month later by using of National Institutes of Health Stroke Scale.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017070921965N7**
Registration date: **2017-08-04, 1396/05/13**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-08-04, 1396/05/13

Registrant information

Name

Homa Zarrabi

Name of organization / entity

Guilan University of Medical Sceinces,«Kavosh » Cognitive Behaviour Sciences and Addiction Researc

Country

Iran (Islamic Republic of)

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+98 13 3366 6268

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shafakavosh@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2017-07-09, 1396/04/18

Expected recruitment end date

2017-11-09, 1396/08/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Clinical trial to evaluate the efficacy of Transcranial Direct Current Stimulations (TDCS) on movement and cognitive functions in patients with subacute brain ischemic stroke

Public title

A Clinical trial to evaluate the efficacy of Transcranial Direct Current Stimulations (TDCS) on movement and cognitive functions in patients with subacute brain ischemic stroke

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with the brain stroke; people aged at least 21 years during 48 hours of their first brain stroke; Exclusion criteria: cardiac pacemaker or metal implants or instruments inside the patient’s body; treatment resistant seizures; using any psychoactive or stimulation drugs; pregnancy; the existence of any neurological condition affecting sensory-motor systems; such as brain tumors; dementia; or severe substance abuse and medications.

Age

From **21 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

For elimination of the possibility of any probable bias due to the knowledge of patients and assessing physicians about the type of treatment we will perform a double blind study. Participants and the evaluating investigators (except the technician that applied TDCS) were blinded to the intervention type. After convenience sampling, the samples will be allocated to the control group, sham group and two intervention groups. The Block Randomization is used for random allocation. This means that patients who entered the study will be randomly assigned number.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Guilan University of Medical Sciences

Street address

Ethics committee of Guilan University of Medical Sciences,Shahid Beheshti Blvd,Opposite to the Sepah bank, Above Iran Radiator Representation. Building Of Assistance Research and Technology, Rasht, Iran

City

Rasht

Postal code

4193893345

Approval date

2017-06-24, 1396/04/03

Ethics committee reference number

IR.GUMS.REC.1396.127

Health conditions studied

1

Description of health condition studied

Ischemic stroke

ICD-10 code

G46

ICD-10 code description

Vascular syndromes of brain in cerebrovascular diseases

Primary outcomes

1

Description

movement and cognitive functions

Timepoint

Treatment effectiveness will be assessed after 15 days, 1 month and 3 month later by using of National Institutes of Health Stroke Scale.

Method of measurement

National Institutes of Health Stroke Scale, REY Verbal Memory Test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1: The treatment will be carried out in 15 sessions, three sessions per week and a consistent, direct and uniform current will be sent to the brain through anodal type waves for up to 30 minutes.

Category

Treatment - Other

2

Description

Intervention group2: The treatment will be carried out in 15 sessions, three sessions per week and a consistent, direct and uniform current will be sent to the brain through cathodal type waves for up to 30 minutes.

Category

Treatment - Other

3

Description

Sham Group: Sham group will get electrical stimulation (TDCS) in the initial moments of each treatment session then the current will be switched off.

Category

Treatment - Other

4

Description

Control group: Control group will not have an electrical stimulation (TDCS) of the brain.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Tooloo Specialty and subspecialty of psychiatry Clinic of Rasht

Full name of responsible person

Dr kiomars Najafi

Street address

Tooloo Specialty and Subspecialty of Psychiatry Clinic ,Shabnam alley, Golsar Crossroads, Opposite to the Municipal of Area (3),Rasht, Iran

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Investigator

Full name of responsible person

Dr kiomars Najafi

Street address

Guilan University of Medical Sciences,15 khordad avenue, Shafa Hospital, Rasht, Iran

City

Rasht

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Investigator

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

Guilan University Of Medical Sciences

Full name of responsible person

Dr Kiomars Najafi

Position

Psychiatrist, Assistant Professor

Other areas of specialty/work

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Guilan University Of Medical Sciences

Full name of responsible person

Mona Musaie

Position

Master Of science in Psychology

Other areas of specialty/work

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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