

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

The effect of cognitive rehabilitation and non-invasive brain stimulation on cognitive abilities and daily living activities of patients after ischemic stroke

Protocol summary

Study aim

Determining the effect of cognitive rehabilitation and non-invasive brain stimulation on cognitive abilities and daily life activities of patients after cerebral ischemic stroke.

Design

Two parallel groups; intervention and sham groups, randomized on 52 patients, double blind study

Settings and conduct

The present study is a study of a double-blind clinical trial. This study will be performed in a clinic affiliated with one of the hospitals in Khorramabad. People who meet the initial criteria will be randomly assigned to the intervention and sham groups after obtaining informed consent. This intervention will generally take 30 to 45 minutes for 4 weeks and 3 sessions each week. It should be noted that both participants in this study and data analyzer will be blind.

Participants/Inclusion and exclusion criteria

People who have had an ischemic stroke for the first time in the last three months have had a score between 1 and 15 on the Modified national of health stroke scale as well as a score of less than 24 on a Mini mental test. It should be noted that patients with a history of anticonvulsant, psychiatric, hypnotic, and muscle relaxant medications will not be included.

Intervention groups

In this study, patients are generally divided into two groups; The intervention group is the group for which cognitive rehabilitation software is used simultaneously with the non-invasive brain stimulation device, and the sham group is the group for which the cognitive rehabilitation software will be used. Nevertheless, the electrodes of the non-invasive stimulation device will be located on patients' skull skin; however, the device will be off.

Main outcome variables

Activities of daily living; RehaCom software screening test scales include: attention and concentration, visual memory, reactive behavior, and logical thinking.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200604047650N1**

Registration date: **2020-08-09, 1399/05/19**

Registration timing: **registered_while_recruiting**

Last update: **2020-08-09, 1399/05/19**

Update count: **0**

Registration date

2020-08-09, 1399/05/19

Registrant information

Name

negin kordestani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-15, 1399/04/25

Expected recruitment end date

2021-04-14, 1400/01/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of cognitive rehabilitation and non-invasive brain stimulation on cognitive abilities and daily living activities of patients after ischemic stroke

Public title

The effect of rehabilitation on stroke

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 40 to 65 years Have a minimum of literacy Patients diagnosed with ischemic stroke in the last three months Ischemia of the right hemisphere of the brain Get a score of less than 24 on a Mini-mental state examination Score between 15-1 in Modified national of health stroke scale

Exclusion criteria:

Disruption of delicate balance movements, especially the right hand Having implantable metal objects (pacemakers, implants, brain clips, etc.) Taking antidepressants, anticonvulsants, hypnotics and muscle relaxants History of previous cerebral ischemic stroke Motor impairment and subsequent inability to visit the clinic

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

Using stratified block random sampling (regarding the homogeneity of groups in terms of gender (female/ male) and the intensity of ischemia (mild/moderate)) and RehaCom software with transcranial direct current stimulation (tdcs), the will divide samples to two intervention and sham groups. In fact, considering the gender and the intensity of ischemia (mild/moderate), 4 strata will be formed in each of them four block random sampling will be used to assign patients to two intervention group and sham group. To this aim, first the researcher will write a list of blocks and assign number them (AABB-ABAB-BBAA-BABA-BAAB) the using random number table, the researcher will randomly select numbers between 1 to 6, and in this way, she will be provided with a list of treatment assignment, based on a sequence of letters A and B.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study will be double blind that is participants and data analysts will be blinded. Participants will all be willing to participate in the study but will not know whether they will be included in the intervention group or the sham one. group members will be fed into the statistical software with a code. Therefore data analyzer will not know to which group the extracted data will belong. Therefore, it will be a double blind study.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Lorestan university of medical sciences

Street address

Nursing and midwifery faculty, Lorestan medical sciences university, 4 kilometers of Khorramabad-Boroujerd road, Khorramabad

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khorrarnabad

Province

Lorestan

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381251698

Approval date

2020-06-06, 1399/03/17

Ethics committee reference number

IR.LUMS.REC.1399.067

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

Cognitive disorders due to cerebral infarction

ICD-10 code

G46.8

ICD-10 code description

Other vascular syndromes of brain in cerebrovascular diseases

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

Cognitive functions

Timepoint

Before intervention and 4 weeks after intervention

Method of measurement

Cognitive evaluation(attention and concentration, visual memory, reactive behavior, and logical thinking) by RehaCom software screening test scale.

Secondary outcomes

1

Description

Basic activity of daily living, Advance activity of daily living

Timepoint

before intervention and 4 weeks after intervention

Method of measurement

Barthel index, Lawton Index

Intervention groups

1

Description

Intervention group: In the intervention group, the researcher uses two methods of non-invasive electrical stimulation intervention and RehaCom rehabilitation software. After the patient is seated in a comfortable chair, where the monitor is in front of him and he has access to the software's keyboard, he is assured of support and support during rehabilitation. Anode and cathode electrodes are placed on the patient's head based on the location of the 10-20 system. The patient is then evaluated by RehaCom software. Based on the results of the evaluation and based on the software proposal, the desired modules are performed with emphasis on the executive functions for the patient. It should be noted that 30 seconds before the start of rehabilitation, the tdcS device is turned on and the stimulation is applied to the patient's scalp in the dorsolateral prefrontal cortex(F3) area through the anode electrode and continues for 20 minutes. It should be noted that while performing brain stimulation, the person is performing cognitive exercises of RehaCom software. Generally, intervention phase will last 12 sessions, 3 sessions a week

Category

Rehabilitation

2

Description

Control group: In the current study, RehaCom's rehabilitation software and non invasive brain stimulation (TDCS) device will also be used for the sham group. In fact, in the sham group, 30 seconds before starting the rehabilitation with RehaCom software, after placing electrodes on the skull, the TDCS will be switched on and the stimulatIn will be applied at a voltage of 2 MA just like that in the intervention group. The only point of difference is that after 30 seconds and simultaneous with the onset of the cognitive rehabilitation the device automatically will shut off. However the rehabilitation will continue using RehaCom. It should be noted that the

intervention will last 12 session, 3 sessions a week. Moreover, the group in which the TDCS device will automatically shut off after 30 seconds is called the sham group.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic No. 2 of Rahimi Hospital

Full name of responsible person

Khadijeh Kazemi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Khoram-Abad 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

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Person responsible for general inquiries**Contact****Name of organization / entity**

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Latest degree

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Latest degree

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Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

As a legal entity, Lorestan University of Medical Sciences owns the data, and as an independent researcher, I do not have the right to publish any data. By obtaining legal permits from Lorestan University of Medical Sciences, information can be provided to others if needed.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available