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 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)

Phone

+98 66 3321 3531

Email address

kordestaninegin@gmail.com

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 hemogeneity 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
City
khorramabad
Province
Lorestan
Postal code
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 invaisive 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 divice 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
Street address
No. 2 Clinic of Rahimi Hospital, Taleghani St, around Governor's Square, Khorramabad
City
Khorramabad
Province
Lorestan
Postal code
6813816314
Phone
+98 66 3333 6141
Email
pirasteh.kazemi@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Khoram-Abad University of Medical Sciences
Full name of responsible person
Ebrahim Fallahi
Street address
Nursing and midwifery school, Lorestan university of medical sciences, 4 km of Khorramabad- Boroujerd road, Khorramabad
City
Khorramabad
Province
Lorestan
Postal code
381251698
Phone
+98 66 3312 0140
Email
kordestaninegin@gmail.com
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

Person responsible for general inquiries

Contact
Name of organization / entity
Khoram-Abad University of Medical Sciences
Full name of responsible person
Negin Kordestani
Position
student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Shahid Kiani Alley, Farzanegan 1 Alley, Naser khosro St, Khorram abad
City
Khorramabad
Province
Lorestan
Postal code
6814955373
Phone
+98 66 3321 3531
Email
kordestaninegin@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Khoram-Abad University of Medical Sciences
Full name of responsible person
parastou kordestani maghaddam
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Neuroscience
Street address
Nursing and midwifery school, Lorestan University of Medical Sciences, 4 km of Khorramabad-Boroujerd road, Kamalvand, Khorramabad
City
Khorramabad
Province
Lorestan
Postal code
381251698
Phone
+98 66 3312 0140
Email
kparastou@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Khoram-Abad University of Medical Sciences
Full name of responsible person
Negin Kordestani
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Shahid Kiani Alley, Farzanegan 1 Alley, Naser khosro St, Khorramabad
City
Khorramabad
Province
Lorestan
Postal code
6814955373
Phone
+98 66 3312 0140
Email
kordestaninegin@gmail.com

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