Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of the order of Transcranial direct current stimulation and Computer-based Cognitive Rehabilitation on Improving Cognitive Performance and Activities of Daily Living Patient with Stroke

Protocol summary

Study aim

Comparison of the effect of the order of Transcranial direct current stimulation and Computer-based Cognitive Rehabilitation on Improving Cognitive Performance and Activities of Daily Living of People with Stroke

Design

Clinical trial with control group, double blind, randomized, with four groups.

Settings and conduct

Sampling will be conducted from Iran University of Medical Sciences hospitals. Interventions will be done in the brain and cognition clinic of the cognitive neuroscience research institute.

Participants/Inclusion and exclusion criteria

Inclusion criteria : diagnosis of ischemic stroke of anterior and medial cerebral arteries or one of the arteries by the neurologist and MRI, No aphasia and associated neurological disorders (Parkinson's, MS, ALS, Alzheimer's), only one stroke ,Post stroke time (1-12 months), Age 20 - 75 years, educated (9 successful grades) . Exclusion criteria: failure to participate in two consecutive treatment sessions, change in medication during the course of the intervention, headache.

Intervention groups

.Interventions include ten sessions each twenty-minute tDCS on c3 or c4 and 30 to 40 minute Captain's log computer based rehabilitation training programs. Therapeutic groups include four groups:Group 1: First tDCS session and then computer based cognitive rehabilitation. Group 2: First, computer based cognitive rehabilitation and then tDCS. Third group: Simultaneously computer based cognitive rehabilitation and tDCS. Group 4:Simultaneously sham tDCS and computer based cognitive rehabilitation.

Main outcome variables

1-Improving executive functions 2-promoting independence in basic and instrumental daily life activities.

General information

Reason for update

Acronym

TDCs

IRCT registration information

IRCT registration number: **IRCT20120910010806N8**
Registration date: **2019-06-15, 1398/03/25**
Registration timing: **retrospective**

Last update: **2019-06-15, 1398/03/25**
Update count: **0**

Registration date

2019-06-15, 1398/03/25

Registrant information

Name

Malahat Akbarfahimi

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-07-23, 1396/05/01

Expected recruitment end date

2018-07-23, 1397/05/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of the order of Transcranial direct current stimulation and Computer-based Cognitive Rehabilitation on Improving Cognitive Performance and Activities of Daily Living Patient with Stroke

Public title
the effect of the order of Transcranial direct current stimulation and Computer-based Cognitive Rehabilitation on Improving Cognitive Performance and Activities of Daily Living
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
schemic stroke in the anterior and medial cerebral arteries or one of the arteries. Neurologist by MRI No aphasia and associated neurological disorders (Parkinson's, MS, ALS, Alzheimer's disease) First stroke of the patient and one to twelve months after the stroke Admission Age Between 20 and 75 Years At least 9 successful grades literacy
Exclusion criteria:
Not attending two consecutive treatment sessions Change the medication during the course of the intervention Create headaches
Age
From **20 years** old to **75 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
By convenient method the records of inpatients and outpatients stroke patients who referred to the department of the neurology of hospitals of Iran University of Medical Sciences between 1 to 12 months ago were reviewed. Then simple randomize method used. The blind person to the aim of the study, divided the eligible patients into four groups by randomization digits table.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study the assessment will be performed by trained assessors who are blind to the study. After completion of the treatment and completing the assessments, the data will be entered into the SPSS and analyzed by the blind person about the four treatment groups.
Placebo
Used
Assignment
Parallel
Other design features
The fourth group of this study receives placebo electrical stimulation, As electrodes are first placed on the headAnd the flow is establishedAnd after 30 seconds, the stream fades out.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran
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۱۴۴۹۶۱۴۵۳۵
Approval date
2018-05-20, 1397/02/30
Ethics committee reference number
IR.IUMS.REC.1398.179

Health conditions studied

1

Description of health condition studied
Cerebral Vascular Accident
ICD-10 code
G46.0
ICD-10 code description
Middle cerebral artery syndrome

2

Description of health condition studied
Cerebral Vascular Accident
ICD-10 code
G46.1
ICD-10 code description
Anterior cerebral artery syndrome

Primary outcomes

1

Description
1-Improvement of executive functions: Spatial Span - One Touch Stockings of Cambridge - latency to correct - mean choices to correct - problem solved on first choices - swtiching cost - Congruency cost - Stop Signal task - direction errors -Proportion of successful stop - reaction time

Timepoint
One day before the first intervention session and one week after the tenth intervention session.

Method of measurement
Cambridge Neuropsychological Test Automated Battery (CANTAB) test.

Secondary outcomes

1

Description
activities of daily living: Those are the skills and tasks that a person pays for them throughout the day and forms the daily routines of the individual's life.These activities include dressing and dressing up, eating, brushing, bathing, going to toilet and dressing yourself. instrumental activities of daily living:These activities are self-care assignments that are usually taught in adolescence and require sophisticated thinking skills, such as the organization of skills.And include activities such as financial management, management of the use of vehicles, purchase of food preparation, traffic management and control how the drugs are.

Timepoint
An initial assessment one day before the start of intervention and a secondary assessment is performed one week after the end of the tenth session of intervention.

Method of measurement
The activities of daily living are assessed by the Barthel index.The instrumental activities of daily living are evaluated by the Lawton scale.

Intervention groups

1

Description
Intervention group: Group 1: First tDCS session on c3 or c4, 2 mA currency for 20 minutes, then computer based cognitive rehabilitation for 30 to 40 minutes, weekly two sessions and ten sessions totally .

Category
Rehabilitation

2

Description
Intervention group: Group 2: First, computer based cognitive rehabilitation for 30 to 40 minutes, and then tDCS on c3 or c4, 2 mA currency for 20 minutes,weekly two sessions and ten sessions totally .

Category
Rehabilitation

3

Description
Intervention group: Group 3: Simultaneously computer based cognitive rehabilitation for 30 to 40 minutes and tDCS on c3 or c4, 2 mA currency for 20 minutes,weekly two sessions and ten sessions totally .

Category
Rehabilitation

4

Description
Control group: Group 4: Simultaneously sham tDCS in such a way that the electrical current is applied only for 30 seconds, and then the current is disconnected, and the device is placed somewhere away from the patient's vision and computer based cognitive rehabilitation for 30 to 40 minutes, weekly two sessionsand ten sessions totally .

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Firuzgar hospital

Full name of responsible person
Mehdi Nikobakht

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2

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Sponsors / Funding sources

1

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Grant name
96-04-32-32633
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran University of Medical Sciences
Proportion provided by this source
30
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

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Other areas of specialty/work

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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