Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The study of transcranial direct current stimulation(tDCS) effect on recovery of the cognitive and linguistic abilities in Persian-Speaking patients with chronic Aphasia.

Protocol summary

Study aim

The aim of this research is to investigate the effects of transcranial direct current stimulation on improvement of severity of aphasia and executive function in patients with aphasia.

Design

This is a single-blind, sham-controlled crossover trial with sample size of 18 patients.

Settings and conduct

In the rehabilitation centers of Hamadan, Patients, randomly receive two types of real and sham stimulation. The participants were assessed for picture-naming and P-WAB-1. Real-tDCS or Sham-tDCS (1 mA- 20 min) was administered for consecutive days followed by a 7-day rest period to avoid carry-over effect. After each tentative condition, and at the end of each real or sham stimulation period, the accuracy and latency of picture-naming and P-WAB-1 were assessed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with Aphasia due to a single left-hemispheric stroke at least 6 months prior to the investigation, age range in 30-80 years, pre-morbid right-handedness . Exclusion criteria: People who have a history of seizer, dementia and psychiatric disorder. Patients who have global aphasia, sever visual or hearing deficits, severe apraxia of speech or oral apraxia, sever dysarthria. Patients who have a history of stroke more than once.

Intervention groups

The intervention and control group are the same. Subjects will be received 5 consecutive real stimulation sessions (20 min, 1mA), and 5 consecutive sham stimulation sessions. The order of conditions will be randomized across subjects.

Main outcome variables

Severity of aphasia; Executive function

General information

Reason for update

Acronym

tDCS

IRCT registration information

IRCT registration number: **IRCT20160509027820N2**
Registration date: **2020-12-02, 1399/09/12**
Registration timing: **prospective**

Last update: **2020-12-02, 1399/09/12**
Update count: **0**

Registration date

2020-12-02, 1399/09/12

Registrant information

Name
Bahareh Rezaei
Name of organization / entity
Hamedan University of Medical Science
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2021-05-20, 1400/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The study of transcranial direct current stimulation(tDCS) effect on recovery of the cognitive and linguistic abilities in Persian-Speaking patients with chronic Aphasia.

Public title
The study of tDCS effect on Aphasia patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with Aphasia due to stroke More than 6 month from stroke onset Age range in 30-80 years Right-handedness Left stroke
Exclusion criteria:
History of seizer, dementia, and neuro-psychological disorders Sever visual or hearing sensory deficits Sever Dysarthria Moderate to sever oral or speech Apraxia More than once stroke Global Aphasia
Age
From **30 years** old to **80 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **18**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
. Subjects will be received 5 consecutive real stimulation sessions (20 min, 1mA), and 5 consecutive sham stimulation sessions. The order of conditions will be randomized across subjects, and the all of patients will be blinded to the type of tDCS.
Placebo
Used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Hamadan University of Medical Sciences
Street address
Vice Chancellery for Research and Technology., Hamadan University of Medical Sciences., Shahid Fahmideh Ave., Hamadan.
City
Hamedan
Province
Hamadan
Postal code
6516705495
Approval date
2020-10-24, 1399/08/03
Ethics committee reference number
IR.UMSHA.REC.1399.652

Health conditions studied

1

Description of health condition studied
Stroke
ICD-10 code
I63.5
ICD-10 code description
Cerebral infarction due to unspecified occlusion or stenosis of cerebral arteries

Primary outcomes

1

Description
Severity of Aphasia
Timepoint
Before intervention, Immediately and one week after intervention
Method of measurement
Score of Persian-Western Aphasia Battery -1 (P-WAB-1)

2

Description
Executive Function
Timepoint
Before intervention, Immediately and one week after intervention
Method of measurement
Score of Wisconsin Card Sorting Test (WCST)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Subjects will participate in 5 consecutive real tDCS sessions (20 min, 1mA). The active electrode (anode) and the reference electrode (cathode) is placed over left superior temporal gyrus (left-STG) and

right supraorbital respectively.

Category

Rehabilitation

2

Description

Control group: Sham transcranial direct current stimulation; the active electrode (anode) and the reference electrode (cathode) is placed over left superior temporal gyrus (left-STG) and right supraorbital respectively. 1 mA current intensity only for the first 30 seconds, turned off current for remained 20 minutes stimulation time.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Mobasher Kashani Rehabilitation Center

Full name of responsible person

Bahareh Rezaei

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Mobasher Kashani Rehabilitation Center., Mahdieh Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

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Vice Chancellery for Research and Technology., Hamadan University of Medical Sciences., Shahid Fahmideh Ave., Hamadan

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Grant name

Grant code / Reference number

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

No

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Bahareh Rezaei

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Speech therapy

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Person responsible for updating data

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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