

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 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 seizure, dementia and psychiatric disorder. Patients who have global aphasia, severe visual or hearing deficits, severe apraxia of speech or oral apraxia, severe 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 3838 1571

##### Email address

e.rezaei@umsha.ac.ir

##### 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**

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**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**

Saeid Bashirian

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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 scientific inquiries****Contact****Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Bahareh Rezaei

**Position**

Assistant professor

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Ph.D.

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## Person responsible for updating data

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**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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## 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