

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### Effect of bihemispheric transcranial direct current stimulation on the verbal function of patients with post-stroke Broca's aphasia during the subacute phase

#### Protocol summary

##### Study aim

Determining the effect of bihemispheric transcranial direct current stimulation on the verbal function of patients with post-stroke Broca's aphasia during the subacute phase

##### Design

A parallel, randomized, double-blinded, clinical trial with a control group

##### Settings and conduct

Considering the interhemispheric inhibition and neuroplastic changes, the aim of this study is to increase the neuronal excitability of the lesioned hemisphere and decrease it in the contralesional hemisphere, using tDCS. This trial will be performed in the neurology ward of Poursina Hospital, in Rasht, Iran. Thirty patients with post-stroke Broca's aphasia will be enrolled and randomly divided into 2 groups, receiving either active or Sham tDCS.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Incidence of aphasia after ischemic stroke, right-handed, literate (able to read and speak in Persian), able to tolerate the treatment process, P-WAB-1 score less than 92, suffering from aphasia based on P-WAB-1 criteria Exclusion criteria: hemorrhagic stroke, tDCS contraindications; metal implants, heart pacemaker, Epilepsy, seizures, taking psychoactive drugs, mental illnesses, pregnancy, brain tumors

##### Intervention groups

- Active tDCS (transcranial direct current stimulation) bihemispheric tDCS with 2 mA intensity will be applied for 20 minutes. Anodal stimulation will be applied to the left hemisphere F5 region. - Sham tDCS Both electrodes will be placed as in active group. Current will be applied for 30 seconds (10 seconds ramp-up, 10 seconds 2 mA and 10 seconds ramp-down). The electrodes remain in place for 20 minutes but no current will be applied to assess the placebo effect.

#### Main outcome variables

Improvement of verbal function based on P-WAB-1 score.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190522043673N1**

Registration date: **2019-08-27, 1398/06/05**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-08-27, 1398/06/05**

Update count: **0**

##### Registration date

2019-08-27, 1398/06/05

##### Registrant information

##### Name

Kambiz Rohampour

##### Name of organization / entity

Guilan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 13 3369 0884

##### Email address

rohampour@gums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-06-22, 1398/04/01

##### Expected recruitment end date

2020-09-21, 1399/06/31

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Effect of bihemispheric transcranial direct current stimulation on the verbal function of patients with post-stroke Broca's aphasia during the subacute phase

**Public title**

Effect of tDCS on post-stroke Broca's aphasia

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Incidence of aphasia after ischemic stroke right handed literate (able to read and speak in Persian) able to tolerate the treatment process P-WAB-1 score less than 92 suffering from aphasia based on P-WAB-1 criteria

**Exclusion criteria:**

hemorrhagic stroke tDCS contraindications; metal implants, heart pacemaker, Epilepsy, seizures, taking psychoactive drugs mental illnesses pregnancy brain tumor

**Age**

From **18 years** old to **80 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **30**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Block randomization will be used; with a block size of 4; Allocation concealment will be performed using sealed envelope software. The participants will be allocated to group A or B, using blocked randomization (Block size: 4). One of the groups receive active tDCS, while the other is sham stimulated, neither the participants nor the allocator is not aware that which group will be the treatment group. The physiotherapist, applying the tDCS, is the only researcher who knows the treatment and the sham group. After treatment (or sham stimulation), the data will be analyzed by the statistician, who is either blind to the data groups.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The participants will be allocated to group A or B, using blocked randomization. Neither the participants nor the allocator is not aware that which group will be the treatment group. The physiotherapist, applying the tDCS, is the only researcher who knows the treatment and the

sham group. After treatment (or sham stimulation), the data will be analyzed by the statistician, who is also blind to the treatment/sham groups.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics committee of Guilan University of Medical Sciences

**Street address**

Poursina Hospital, Namjou street, Emam blvd.

**City**

Rasht

**Province**

Guilan

**Postal code**

41937-13194

**Approval date**

2019-05-11, 1398/02/21

**Ethics committee reference number**

IR.GUMS.REC.1398.069

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

post-stroke broca's aphasia

**ICD-10 code**

169.320

**ICD-10 code description**

Aphasia following cerebral infarction

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

P-WAB-1 score

**Timepoint**

Before intervention - After intervention - 3 month after intervention

**Method of measurement**

P-WAB-1 questionnaire

**Secondary outcomes**

empty

## Intervention groups

### 1

#### Description

- Active tDCS (transcranial direct current stimulation); bihemispheric tDCS with 2 mA intensity will be applied for 20 minutes. Anodal stimulation will be applied to the left hemisphere F5 region.

#### Category

Treatment - Devices

### 2

#### Description

- Sham tDCS; Both electrodes will be placed as in active group. Current will be applied for 30 seconds (10 seconds ramp-up, 10 seconds 2 mA and 10 seconds ramp-down). The electrodes remain in place for 20 minutes but no current will be applied to assess the placebo effect.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Poursina Hospital

##### Full name of responsible person

Soha Yekta

##### Street address

Namjou street, Emam blvd.

##### City

Rasht

##### Province

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##### Postal code

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##### Phone

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##### Fax

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##### Email

poursina@gums.ac.ir

##### Web page address

<http://www.gums.ac.ir/poursina>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Guilan University of Medical Sciences

##### Full name of responsible person

Shademan Nemati

##### Street address

Shahid Beheshti Blvd.(west), opposite of Sepah Bank, vice-chancellor for Research Building

##### City

Rasht

##### Province

Guilan

##### Postal code

4193853948

##### Phone

+98 13 3336 2889

##### Fax

+98 13 3336 2842

##### Email

research@gums.ac.ir

##### Web page address

<http://www.gums.ac.ir/research>

#### Grant name

Vice Chancellor for Research of Guilan University of Medical Sciences

#### Grant code / Reference number

97122203

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

Yes

#### Title of funding source

Guilan 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

Guilan University of Medical Sciences

##### Full name of responsible person

Kambiz Rohampour

##### Position

Assistant professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Neuroscience

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

Associate professor

**Latest degree**

Specialist

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Neurology

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## Person responsible for updating data

### Contact

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**Full name of responsible person**

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**Position**

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**Latest degree**

Specialist

**Other areas of specialty/work**

Neurology

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**Phone**

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**Email**

Alia.saberi.1@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**

There is no further information

**Study Protocol**

Undecided - It is not yet known if there will be 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**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable