

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

### Clinical trial to evaluate the efficacy of electrical stimulation of the brain with direct electrical current on depression after stroke

#### Protocol summary

##### Summary

This study will be designed as a double-blind clinical trial to assess the efficacy of brain Stimulation therapy on depression after stroke. Sample size consists of is 150 patients with stroke who referred to the specialized clinic of Toloo in Rasht. Patients are selected by a psychiatrist based on clinical interview according to Diagnostic and Statistical Manual of Mental Disorders (DSM-5). After signing the informed consent and considering inclusion and exclusion criteria, Patients with stroke will enter the study by Convenience sampling. After sampling, the samples will be allocated to the control group and two intervention groups. Exclusion criteria will be defined by a history of epilepsy or patients unwillingness to participate in the study. Treatment will be carried out in fifteen sessions, three sessions per week, and a direct and continuous electrical stimulation will be sent the cortex through electrodes for a maximum duration of thirty minutes. Treatment effectiveness will be assessed on 15 days, 1 month 3 month later according to Beck depression questionnaire, second edition.

#### General information

##### Acronym

-

##### IRCT registration information

IRCT registration number: **IRCT2017030921965N4**

Registration date: **2017-05-28, 1396/03/07**

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

Last update:

Update count: **0**

##### Registration date

2017-05-28, 1396/03/07

##### Registrant information

###### Name

Homa Zarrabi

##### Name of organization / entity

Guilan University of Medical Sciences, «Kavosh »

Cognitive Behaviour Sciences and Addiction Research

##### Country

Iran (Islamic Republic of)

##### Phone

+98 13 3366 6268

##### Email address

shafakavosh@gums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Investigator

##### Expected recruitment start date

2017-03-09, 1395/12/19

##### Expected recruitment end date

2017-07-10, 1396/04/19

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Clinical trial to evaluate the efficacy of electrical stimulation of the brain with direct electrical current on depression after stroke

##### Public title

Clinical trial to evaluate the efficacy of electrical stimulation of the brain with direct electrical current on depression after stroke

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Patients with the brain stroke, people aged at least 21 years during 48 hours of their first brain stroke; Exclusion criteria: cardiac pacemaker or metal

implants or instruments inside the patient's body, treatment resistant seizures, using any psychoactive or stimulation drugs, pregnancy, the existence of any neurological condition affecting sensory-motor systems, such as brain tumors, dementia, or severe substance abuse and medications and Severe cognitive declines.

#### Age

From **21 years** old to **50 years** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **150**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

For elimination of the possibility of any probable bias due to the knowledge of patients and assessing physicians about the type of treatment we will perform a double blind study. Participants and the evaluating investigators (except the technician that applied tDCS) were blinded to the intervention type. After convenience sampling, the samples will be randomly entered into intervention and control groups. The sealed envelope is used for random allocation.

## Secondary Ids

### 1

#### Registry name

-

#### Secondary trial Id

-

#### Registration date

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Guilan University of Medical Sciences

##### Street address

Shahid Beheshti Blvd, Opposite to the Sepah bank, Above Iran Radiator Representation. Building Of Assistance Research and Technology, Rasht, Iran

##### City

Rasht

#### Postal code

4193893345

#### Approval date

2016-11-12, 1395/08/22

#### Ethics committee reference number

IR.GUMS.REC.1395.273

## Health conditions studied

### 1

#### Description of health condition studied

Depressive episode

#### ICD-10 code

F32

#### ICD-10 code description

Depressive episode

## Primary outcomes

### 1

#### Description

Depression

#### Timepoint

Treatment effectiveness will be assessed on 15 days, 1 month and 3 month later.

#### Method of measurement

Beck Depression questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group1: The treatment will be carried out in 15 sessions, three sessions per week and a consistent, direct and uniform current will be sent to the brain through anodal type waves for up to 30 minutes.

#### Category

Treatment - Other

### 2

#### Description

Control group: The control group will get electrical stimulation (TDCS) in the initial moments of each treatment session then the current will be switched off.

#### Category

Treatment - Other

### 3

#### Description

Intervention group2: The treatment will be carried out in 15 sessions, three sessions per week and a consistent, direct and uniform current will be sent to the brain

through cathodal type waves for up to 30 minutes.

**Category**

Treatment - Other

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Tooloo Specialty and subspecialty of psychiatry Clinic of Rasht

**Full name of responsible person**

Dr kiomars Najafi

**Street address**

Shabnam alley, Golsar Crossroads, Opposite to the Municipal of Area (3), Rasht, Iran

**City**

Rasht

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Investigator

**Full name of responsible person**

Dr Homa Zarrabi

**Street address**

15 khordad avenue, Shafa Hospital, Rasht, Iran Rasht Guilan

**City**

Rasht

**Grant name**

-

**Grant code / Reference number**

-

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

Yes

**Title of funding source**

Investigator

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Guilan University Of Medical Sciences

**Full name of responsible person**

Dr Homa Zarrabi

**Position**

Psychiatrist, Assistant Professor

**Other areas of specialty/work**

**Street address**

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+98 13 3366 6268

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**Web page address**

-

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Master Of science in I Psychology

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*