

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)

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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

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Master Of science in I Psychology

Other areas of specialty/work

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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