

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

The Effect of transcranial Direct Current Stimulation on the Reduction of Negative Symptoms in Schizophrenic Patients

Protocol summary

Negative sign of Schizophrenia

Study aim

The Effect of transcranial Direct Current Stimulation on the Reduction of Negative Symptoms in Schizophrenic Patients

Design

This clinical trial has a community-based control group with parallel groups. This is a randomized, double-blind, phase 2-3 study with 32 patients. Randomization will be done using random numbers created by the computer. The patient and the outcome assessor are not aware of the type of intervention.

Settings and conduct

Qualified patients will be randomly divided into two intervention tDCS and control tDCS groups. Accidental randomization will be performed based on blocking. This clinical trial has a community-based, action-oriented control group with parallel and double-blind groups. The patient and the evaluator do not know the type of intervention, the type of block, and the sample size in each block. this study will done in Golestan hospital, Ahvaz

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of DSM-5 schizophrenia, no liver disease, no history of treatment with direct transcranial electrical during the last six months, duration of illness should be more than one year and age over 18 years. Exclusion criteria: Patient with depression; bipolar disorder; epilepsy and Parkinson's; pregnant or breastfeeding woman and drug abuse in recent months

Intervention groups

Qualified patients based on criteria will be randomly divided into two groups of tDCS and fictitious tDCS. Intervention group: The true tDCS group will receive 2 sessions of the right anode and left cathode. The intervention will do randomly for 20 minutes and 2 mA on the lateral posterior frontal area. Control group: the right anode and left cathode will place on the forehead but the machine will not turn on.

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100520003979N10**

Registration date: **2021-08-02, 1400/05/11**

Registration timing: **prospective**

Last update: **2021-08-02, 1400/05/11**

Update count: **0**

Registration date

2021-08-02, 1400/05/11

Registrant information

Name

Forugh Riahi

Name of organization / entity

Ahvaz Jundishapour University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-23, 1400/06/01

Expected recruitment end date

2021-10-23, 1400/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of transcranial Direct Current Stimulation on the Reduction of Negative Symptoms in Schizophrenic Patients

Public title

The Effect of transcranial Direct Current Stimulation on Schizophrenic Patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Diagnosis of schizophrenia based on DSM-5 No liver disease No history of treatment with direct transcranial electrical during the last six months The duration of the disease is more than one year Age over 18 years old

Exclusion criteria:**Age**

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment will be done by the use of computer-generated random numbers

Blinding (investigator's opinion)

Double blinded

Blinding description

The double-blind side includes the patient and the person who is responsible for assessing the outcome. The patient knows that he has participated in a study but does not know what treatment is receiving. The assessor does not know which patient was involved in the intervention group.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee**

Name of ethics committee

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Golestan Blvd, Ahvaz, Khoozestan

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Province

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Postal code

6135715794

Approval date

2021-02-02, 1399/11/14

Ethics committee reference number

IR.AJUMS.HGOLESTAN.REC.1399.149

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

Schizophrenia

ICD-10 code

F20

ICD-10 code description

Schizophrenia

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

Negative signs of Schizophrenia

Timepoint

At the start of treatment, weeks 2, 4

Method of measurement

Overall scale score PANS

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: The true tDCS group will receive 2 sessions of the right anode and left cathode stimulation sessions by an experienced technician with no knowledge of the subject and an interventional therapist. The intervention will do randomly for 20 minutes and 2 mA on the lateral posterior frontal area

Category

Treatment - Other

2**Description**

Control group: the right anode and left cathode will place on the forehead by an experienced technician with no knowledge of the subject but the machine will not turn on.

Category

Treatment - Other

Country of origin**Type of organization providing the funding**

Academic

Recruitment centers**1****Recruitment center****Name of recruitment center**

Psychiatry Clinic, Golestan Hospital

Full name of responsible person

Seyyed Mohmmad Hasani

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Ahvaz 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

Person responsible for general inquiries**Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Forough Riahi

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Psychiatrics

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Person responsible for updating data**Contact****Name of organization / entity**

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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