

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of trans cranial direct current stimulation of the brain(tdcs)on cognitive deficit in inpatients with schizophrenia

Protocol summary

Study aim

The effect of trans cranial direct current stimulation of the brain(tdcs)on cognitive deficit in inpatients with schizophrenia

Design

Patients with Schizophrenia admitted to the psychiatric ward of Amir Kabir Hospital in Arak are included in the study. The sample size is 20 people who are Simple randomization with random number to two groups. study is clinical trial and double-blind.

Settings and conduct

Patients with Schizophrenia admitted to the psychiatric ward of Amir Kabir Hospital in Arak are included in the study. The sample size is 20 people who are Simple randomization with random number to two groups. study is clinical trial and double-blind. The patient is not aware of the treatment received. Participant and Analyzer are blind (double blind).

Participants/Inclusion and exclusion criteria

Inclusion criteria: 18-60 years, the presence of criteria for schizophrenia disorder based on DSM IV-TR criteria and clinical interview conducted by the supervisor, no received ECT within one month before entering the study, lack of mental retardation Exclusion criteria: The incidence of side effects that makes the patient unwilling to continue tDCS, need for ECT, epilepsy, dementia, delirium and other cognitive disorders, not pregnancy, lack of medical illness, abuse of substance or alcohol during the last month, except nicotine

Intervention groups

We place 10 patients in the case group and 10 patients in the control group. In the control group, the electrodes are attached but do not stimulate. In the case group, a direct brain electrical stimulation begins with the tDCS device (Medina Medical Manufacturing Company of the United Kingdom). The current is 2 milliAmper for 20 minutes each day for 10 sessions.

Main outcome variables

Working memory, continuous attention, selective

attention and executive performance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N79**

Registration date: **2018-06-02, 1397/03/12**

Registration timing: **registered_while_recruiting**

Last update: **2018-06-02, 1397/03/12**

Update count: **0**

Registration date

2018-06-02, 1397/03/12

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3222 2003

Email address

f.farokhi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-06-20, 1396/03/30

Expected recruitment end date

2019-06-20, 1398/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of trans cranial direct current stimulation of the brain(tdcs)on cognitive deficit in inpatients with schizophrenia

Public title

The effect of trans cranial direct current stimulation of the brain(tdcs)on cognitive deficit in inpatients with schizophrenia

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

18-60 yeaqrs The presence of criteria for schizophrenia disorder based on DSM IV-TR criteria and clinical interview conducted by the supervisor no received ECT within one month before entering the study Lack of mental retardation

Exclusion criteria:

The incidence of side effects that makes the patient unwilling to continue tDCS Need for ECT Epilepsy, dementia, delirium and other cognitive disorders Not pregnancy Lack of medical illness Abuse of substance or alcohol during the last month, except nicotine

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization with random number in division of groups

Blinding (investigator's opinion)

Double blinded

Blinding description

Randomized allocation in clinical trial studies refers to the process of dividing participants into different groups randomly. Randomizing gives each participant equal odds for being placed in each of the groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee Arak University Of Medical Sciences

Street address

Vice Chancellor for Research, Payambar Azam Complex, Basij Squire, Sardasht, Arak

City

Arak

Province

Markazi

Postal code

3814957558

Approval date

2017-05-22, 1396/03/01

Ethics committee reference number

IR.ARAKMU.REC.1396.34

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

Schizophrenia

ICD-10 code

F20

ICD-10 code description

Schizophrenia

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

Working memory

Timepoint

Before starting Tdcs, after 5 sessions and one day after 10 sessions

Method of measurement

Continuous Performance Test

2**Description**

continuous attention

Timepoint

Before starting Tdcs, after 5 sessions and one day after 10 sessions

Method of measurement

Continuous Performance Test

3**Description**

selective attention

Timepoint

Before starting Tdcs, after 5 sessions and one day after 10 sessions

Method of measurement

4**Description**

executive performance

Timepoint

Before starting Tdcs, after 5 sessions and one day after 10 sessions

Method of measurement

Wechsler Test

Secondary outcomes

empty

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

Control group: In the control group, the electrodes are attached but do not stimulate.

Category

Treatment - Other

2**Description**

Intervention group: In the case group, a direct brain electrical stimulation begins with the tDCS device (Medina Medical Manufacturing Company of the United Kingdom). The current is 2 milliAmper for 20 minutes each day for 10 sessions.

Category

Treatment - Other

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

Amirkabir hospital

Full name of responsible person

Dr Anita Alagheman

Street address

Amirkabir hospital, Parastar Square

City

Arak

Province

Markazi

Postal code

3814957558

Phone

+98 86 3222 2003

Fax

+98 86 3222 2003

Email

alaghemand@arakmu.ac.ir

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

Arak University of Medical Sciences

Full name of responsible person

Dr Arjmandzadegan

Street address

Vice chancellor for research, Payambar Azam Complex, Basij square, Sardasht, Arak

City

Arak

Province

Markazi

Postal code

3814957558

Phone

+98 86 3222 2003

Fax

+98 86 3222 2003

Email

Arjmandzadegan@arakmua.ac.ir

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

Yes

Title of funding source

Arak 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**

Arak University of Medical Sciences

Full name of responsible person

Dr Mohsen Ghasemi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Street address

Amirkabir hospital, Parastar square

City

Arak

Province

Markazi

Postal code
3814957558
Phone
+98 86 3222 2003
Fax
+98 86 3222 2003
Email
ghasemi@arakmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr Anita Alaghemand
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
Street address
Amirkabir hospital, Parastar square
City
Arak
Province
Markazi
Postal code
3814957558
Phone
+98 86 3222 2003
Fax
+98 86 3222 2003
Email
Alaghemand@arakmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr Maryam Kavei
Position
resident of psychology
Latest degree
Specialist

Other areas of specialty/work
Psychiatrics
Street address
Amirkabir hospital, Parastar square
City
Arak
Province
Markazi
Postal code
3814957558
Phone
+98 86 3222 2003
Fax
+98 86 3222 2003
Email
marmar_kaveh64@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

When we publish relevant article in a journal.

When the data will become available and for how long

After publishing the article

To whom data/document is available

researchers who work at university

Under which criteria data/document could be used

If there are additional questions

From where data/document is obtainable

Dr Anita Alaghemand

What processes are involved for a request to access data/document

They have to send their request to the professor who is the chair of the work and they also must pass administrative process of the university.

Comments