

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Sep 2026

Evaluation of the effects of transcranial direct current stimulation on geriatric depression

Protocol summary

Study aim

Evaluation of the effects of transcranial direct current stimulation on geriatric depression

Design

Two arm parallel group randomized trial with blinded tdc effect. group of 90 patients. 45 case and 45 control

Settings and conduct

geriatric patients who referred to geriatric clinic of psychiatry institute will be tested with geriatric depression scale. and the positive ones will be chosen. after registration of demographic data, based on entrance and exit criteria 90 patients will enter the trial. they will be divided in two equal groups based on block randomization. all the patients will receive sertraline with initial dose of 25 mg and increase dose up to 50mg. and 5 period of electrical stimulation, 2 milliampere currents in 20 minutes, with protocol of anode in f3 and supraorbital cathode will be perform in case group, with off tdc stimulation in control group. GDS will perform after the third session one time and 1 month after the end of the intervention for the third time. and the result will be comprise between tow groups.

Participants/Inclusion and exclusion criteria

entrance criteria: geriatric more than 60 years old with depression diagnosis in geriatric depression scale exit criteria: metal in skull area

Intervention groups

Intervention group: 45 geriatric patient with positive geriatric depression scale test which recessive combination therapy with sertraline 50 mg daily and transcranial direct current stimulation 1-2 mA in 5 sessions of 20 minutes period . control group: 45 geriatric patient with positive geriatric depression scale test which recessive just sertraline 50 mg daily.

Main outcome variables

GDS score after third session of TDCS GDS score after fifth session of TDCS GDS score one month after completion of treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181215041976N1**

Registration date: **2019-03-10, 1397/12/19**

Registration timing: **registered_while_recruiting**

Last update: **2019-03-10, 1397/12/19**

Update count: **0**

Registration date

2019-03-10, 1397/12/19

Registrant information

Name

Mahsa Zareie

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6655 0200

Email address

zareii.m@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-22, 1397/10/01

Expected recruitment end date

2019-12-22, 1398/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effects of transcranial direct current stimulation on geriatric depression

2019-01-17, 1397/10/27

Ethics committee reference number
IR.IUMS.REC.1397.574

Public title

effects of transcranial direct current stimulation on geriatric depression

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

geriatric older than 60 with depression in geriatric depression scale

Exclusion criteria:

metal skull area seizure history history of allergy with TDCS

Age

From **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Block Randomization

Blinding (investigator's opinion)

Single blinded

Blinding description

OFF TDCS in control group

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of IRAN University of Medical Science

Street address

No. 1, Mansouri St., Niyayesh St. , Sattarkhan St., Tehran, Tehran Institute of Psychiatry

City

Tehran

Province

Tehran

Postal code

1

Approval date

Health conditions studied

1

Description of health condition studied

depression

ICD-10 code

F32.9

ICD-10 code description

Depressive episode, unspecifiedDepression

NOSDepressive disorder NOS

Primary outcomes

1

Description

geriatric depression score

Timepoint

before tdcs and 3, 5 and 30 days after first tdcs

Method of measurement

geriatric depression scale test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 45 geriatric patient with positive geriatric depression scale test which recessive combination therapy with serteraline 50 mg daily and transcranial direct current stimulation 1-2 mA in 5 sessions of 20 minutes period .

Category

Rehabilitation

2

Description

Control group: 45 geriatric patient with positive geriatric depression scale test which recessive serteraline 50 mg daily and the same pattern of tDCS but off mode.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Geriatric clinic

Full name of responsible person

Dr. Mahsa Zareie

Street address

No.1, Mansouri St., Niyayesh St., Sattarkhan St.,
Tehran, Tehran institute of psychiatry

City

Tehran

Province

Tehran

Postal code

1

Phone

+98 21 6655 1515

Email

zareii.m@iums.ac.ir

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Geriatrics

Street address

No. 1, Mansouri St., Niyayesh St. , Sattarkhan St.,
Tehran, Tehran Institute of Psychiatry

City

Tehran

Province

Tehran

Postal code

1

Phone

+98 21 6655 1515

Email

zareii.m@iums.ac.ir

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

Iran University of Medical Sciences

Full name of responsible person

Dr. seyyed Kazem Malakouti

Street address

No. 1, Mansouri St., Niyayesh St. , Sattarkhan St.,
Tehran, Tehran Institute of Psychiatry

City

Tehran

Province

Tehran

Postal code

1

Phone

+98 21 6655 1515

Email

zareii.m@iums.ac.ir

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

Yes

Title of funding source

Iran 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**

Iran University of Medical Sciences

Full name of responsible person

Mahsa Zareie

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

Iran University of Medical Sciences

Full name of responsible person

Mahsa Zareie

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Geriatrics

Street address

No. 1, Mansouri St., Niyayesh St. , Sattarkhan St.,
Tehran, Tehran Institute of Psychiatry

City

Tehran

Province

Tehran

Postal code

1

Phone

+98 21 6655 1515

Email

zareii.m@iums.ac.ir

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

Iran University of Medical Sciences

Full name of responsible person

Mahsa Zareie

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Geriatrion

Street address

No. 1, Mansouri St., Niyayesh St. , Sattarkhan St.,
Tehran, Tehran Institute of Psychiatry

City

Tehran

Province

Tehran

Postal code

1

Phone

+98 21 6655 1515

Email

zareii.m@iums.ac.ir

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

No - There is not 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

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available