

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Title: Clinical trial of efficacy of Trans cranial direct current stimulation (TDCS) in reducing post-traumatic stress signs in military post-traumatic stress disorder

Protocol summary

Study aim

The aim of this study was designed to evaluate the effect of treatment with brain electric stimulation on the symptoms of military post traumatic stress disorder patients as a double blind clinical trial.

Design

This study will be designed as a double blind clinical trial In the third phase. The target population of this study will be 60 patients with post traumatic stress disorder who referred to the Toloo Specialist Clinic in Rash.

Settings and conduct

The target population of this study will be 60 patients with post traumatic stress disorder who referred to the Toloo Specialist Clinic in Rash. Patients will be selected by a psychiatrist based on clinical interviews.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with military post traumatic stress disorder; Age: 18 to 60 years; Non-inclusion criteria: existence of any neurological condition; low IQ; unwillingness to participate in the study

Intervention groups

Intervention group1: During treatment straight and uniform Electrical current will be sent to the brain through cathodal type waves for up to 30 minutes. Then this group will be entered into the Sham program for 12 session. Sham program will get electrical stimulation (TDCS) in the initial moments of each treatment session then the current will be switched off. Intervention group2: In the first 12 sessions will be entered into the Sham program. Control group: will not have an electrical stimulation (TDCS) of the brain.

Main outcome variables

Symptoms Post-traumatic Stress Disorder

General information

Reason for update

Acronym

TDCS

IRCT registration information

IRCT registration number: **IRCT20150427021965N9**

Registration date: **2018-06-08, 1397/03/18**

Registration timing: **retrospective**

Last update: **2018-06-08, 1397/03/18**

Update count: **0**

Registration date

2018-06-08, 1397/03/18

Registrant information

Name

Homa Zarrabi

Name of organization / entity

Guilan University of Medical Sceinces, «Kavosh »
Cognitive Behaviour Sciences and Addiction Researc

Country

Iran (Islamic Republic of)

Phone

+98 13 3366 6268

Email address

shafakavosh@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-10, 1396/11/21

Expected recruitment end date

2018-02-10, 1396/11/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Title: Clinical trial of efficacy of Trans cranial direct current stimulation (TDCS) in reducing post-traumatic stress signs in military post-traumatic stress disorder

Public title

Title: Clinical trial of efficacy of Trans cranial direct current stimulation (TDCS) in reducing post-traumatic stress signs in military post-traumatic stress disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with military post traumatic stress disorder Age 18 to 60 years

Exclusion criteria:

existence of any neurological condition low IQ Any metal implants or instruments inside the patient's skull or brain Any side effect due to treatment intervention unwillingness to participate in the study substances-dependency to stimulants in past 6 month patient have bipolar disorder or psychotic disorder exacerbation of patient symptoms that need any emergency intervention or elevate in drug dose .

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

After convenience sampling, Participants will be assigned to three groups of 20 people using closed envelopes with blocked randomization method. Blocking will be used to create the number of samples assigned to each treatment group. In this study, people will be divided into 10 blocks of 6.

Blinding (investigator's opinion)

Double blinded

Blinding description

For elimination of the possibility of any bias due to the knowledge of patients or physicians evaluation of the results, and possible impact on the outcomes of research a double blind study will be performed, Participants and the evaluating investigators (except the technician that applied TDCS) will be blind to the intervention type.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

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 vice chancellor Research and Technology, Rasht, Iran

City

Rasht

Province

Guilan

Postal code

4193893345

Approval date

2017-11-25, 1396/09/04

Ethics committee reference number

IR.GUMS.REC.1396.422

Health conditions studied

1

Description of health condition studied

post-traumatic stress disorder

ICD-10 code

F43.1

ICD-10 code description

Post-traumatic stress disorder (PTSD): rises as a delayed or protracted response to a stressful event or situation (of either brief or long duration) of an exceptionally threatening or catastrophic nature, which is likely to cause pervasive distress in alm

Primary outcomes

1

Description

Depression Score in the Beck's Questionnaire

Timepoint

The effectiveness of the treatment will be evaluated in the twelve, twenty-four, and one-month follow-up sessions.

Method of measurement

The effectiveness of the treatment will be evaluated based on the score obtained from the Beck Depression questionnaire.

2

Description

Anxiety Score in Beck's Questionnaire

Timepoint

The effectiveness of the treatment will be evaluated in the twelve, twenty-four, and one-month follow-up sessions.

Method of measurement

The effectiveness of the treatment will be evaluated based on the score obtained from the Beck Anxiety questionnaire.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1: During treatment straight and uniform Electrical current will be sent to the brain through Cathodal type waves for up to 30 minutes. Then this group will be entered into the Sham group for 12 session. Sham group will get electrical stimulation Transcranial direct current stimulation (TDCS) in the initial moments of each treatment session then the current will be switched off.

Category

Treatment - Other

2

Description

Intervention group2: Intervention group2: . Sham group will get electrical stimulation (TDCS) in the initial moments of each treatment session then the current will be switched off. In the 12 second days the treatment will be carried out in 12 consecutive sessions and straight and uniform Electrical current will be sent to the brain through Cathodal type waves for up to 30 minutes.

Category

Treatment - Other

3

Description

Control group: Group will not have an electrical stimulation (TDCS) of the brain.

Category

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

Province

Guilan

Postal code

41939-55599

Phone

+98 13 3366 6268

Email

Kkiomars@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Dr Mirsaeed Attarchi

Street address

Namjoo Street, University Of Medical Sciences
Guilan, Vice Chancellor for Research, Rasht, Iran

City

Rasht

Province

Guilan

Postal code

93345-41938

Phone

+98 13 3336 2772

Email

msattarchi@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Rasht University of Medical Sciences

Proportion provided by this source

50

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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Dr Kiomars Najafi

Position

Associate professor

Latest degree

Specialist
Other areas of specialty/work
Psychiatrics
Street address
15 khordad Avenue, Shafa Hospital, Rasht, Iran
City
Rasht
Province
Guilan
Postal code
41939-55599
Phone
+98 13 3366 6268
Email
Kkiomars@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Dr Kiomars Najafi
Position
Associate Professor
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
Street address
15 khordad Avenue, Shafa Hospital, Rasht, Iran
City
Rasht
Province
Guilan
Postal code
41939-55599
Phone
+98 13 3366 6268
Email
Kkiomars@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Aida yahyazadeh
Position
Researcher

Latest degree
Master
Other areas of specialty/work
Psychology
Street address
15 Kordad Avenue, Shafa Hospital, Rasht, Iran
City
Rasht
Province
Guilan
Postal code
41939-55599
Phone
+98 13 3311 3995
Email
aidayahyazadeh@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

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

All data will be available to researchers through contact with the designer's email.

When the data will become available and for how long

After publishing the article and analyzing the data

To whom data/document is available

After publishing the article and analyzing the data

Under which criteria data/document could be used

Only non-analyzed data will be available to researchers.

From where data/document is obtainable

DR Kiomars Najafi, Tooloo Specialty and subspecialty psychiatry Clinic, Rasht, Shabnam alley, in front of Area 3 municipslity, Golsar Crossroads, Rasht, Iran.
kkiomars@yahoo.com

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

kkiomars@yahoo.com

Comments