Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effect of trance cranial direct current electrical stimulation plus cranial electrothrapy stimulation rather than trance cranial direct current stimulation in treatment of major depression disorder.

Protocol summary

Summary

Comparison of two methods of trance cranial direct electrical stimulation plus cranial electrotherapy stimulation rather than trance cranial direct electrical stimulation lonely in the treatment of major depression, it is a double-blind randomized clinical trial study with a control group (sham) as a placebo on 30 patients with major depression, the 30 patients after semi-structured interviews with the consent of a study by a psychiatrist, patients with chronic physical illness or mental disorders or defects of the skull. The numbers are in three groups: in control group to eliminate placebo effect of TDCS we use active cs device with inactive tdcs(sham) in group B we use active TDCS device and inactive CES as sham.) Group C (both devices (tDCS) and (CES)are active, each device are used for patient separately for 20 minutes and frequency of devices are adjust upon of QEG has been taken from each patient before the intervention. Before and after the last session patient fill Beck questioner of depression t, not the patient nor the analyst is not aware of the type of treatment effectiveness of treatments carried out on the basis of changes in Depression Inventory scores before and after treatment are calculated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015051122176N2**
Registration date: **2015-06-22, 1394/04/01**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-06-22, 1394/04/01

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Shahid Sadoghi University of Medical Sciences, Yazd

Expected recruitment start date

2014-12-24, 1393/10/03

Expected recruitment end date

2015-04-30, 1394/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of trance cranial direct current electrical stimulation plus cranial electrothrapy stimulation rather than trance cranial direct current stimulation in treatment of major depression disorder.

Public title

Trance cranial direct current electrical stimulation plus cranial electrothrapy stimulation rather than trance cranial direct current stimulation in treatment of major depression disorder.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: major depression that diagnosed during a semi-structured interviews by psychiatrists on DSMIV-TR and having ultimately up to the age and sign a consent. Exclusion criteria: other major psychiatric disorders such as active psychosis; suicidal thoughts and suicide; abusie or dependency on any substance (except caffeine); other anxiety disorders except mild to moderate anxiety followed by depression (Beck Anxiety Inventory score under 21); lack of physical illness itself as a chronic stressor act during illness the lack of a defect in the skull, scalp; foreign bodies in the brain; lack of grief or mourning the loss of a close relationship between the patient; there is no criteria for personality disorder as a disease in a patient during an interview on DSMIV-TR; the absence of disease; neurological especially active seizure and pregnancy.

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Sadoghi University of Medical Sciences, Yazd

Street address

Pardise Medical University of Yazd

City

Yazd

Postal code

Approval date

2015-04-23, 1394/02/03

Ethics committee reference number

ir.ssu.medicine.rec. 1393.127

Health conditions studied

1

Description of health condition studied

Major deppresion disorder

ICD-10 code

F32

ICD-10 code description

Depressive episode

Primary outcomes

1

Description

depression

Timepoint

9 days

Method of measurement

beck depression questionary

Secondary outcomes

1

Description

side effectes of intervenion devices

Timepoint

after the last session

Method of measurement

examination by medical doctor

Intervention groups

1

Description

IN FIRST international group 10 patients who has chosen double blined randomised recive both devices (tDCS) AND (CES) IN ACTIVE form for 6 sessions that first three sessions are daily and the three other are with 1day interval

Category

Treatment - Devices

2

Description

In group B of intervention 10 patients in double blind randomised clincal traial recived (tDCS) in sctive way and (Ces) in actively as (sham) in 6 sessions that first 3 sessions are daily and the 3 others are with one day interval, an each devices are used 20 minutes separately

Category

Treatment - Devices

3

Description

Group c , is control group that used for vanished the placebo effect of (tDCS),fore that reason 10 patients that

chosen randomly in double blinde clincal traial, eith the active form of(CES) and in active form of (tDCS)for 6 sessions that first 3 sessions are daily and the other 3 sessions are with 1 day interval, each device is use d separately for 20 minutes

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Baghaeipour Clinical Centre

Full name of responsible person

Dr. Ghasem Dastjerdi

Street address

Shahid Sadoughi hospital

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Sadoghi University of Medical Sciences, Yazd

Full name of responsible person

Dr. Ghasem Dastjerdi

Street address

Psychiatry Research Center, Yazd

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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

Shahid Sadoghi University of Medical Sciences, Yazd

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

Jundishapoor University of Medical Sciences

Full name of responsible person

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Position

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Other areas of specialty/work

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Person responsible for updating data

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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