

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 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

##### Name

Ehsan Mohammadi

##### Name of organization / entity

Joundishapoor University of Ahvaz

##### Country

Iran (Islamic Republic of)

##### Phone

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##### Email address

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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; abusive 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 depression disorder

#### **ICD-10 code**

F32

#### **ICD-10 code description**

Depressive episode

## **Primary outcomes**

### **1**

#### **Description**

depression

#### **Timepoint**

9 days

#### **Method of measurement**

beck depression questionnaire

## **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 blinded 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 clinical trial recived (tDCS ) in active 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 clinical 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

**City**

Yazd

**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**

Dr. Ehsan Mohammadi

**Position**

MD, resistant of psychology

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**Position**

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**Other areas of specialty/work****Street address**

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**City**

Shiraz

**Postal code****Phone****Fax****Email****Web page address****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*