

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### Therapeutic effects of transcranial direct current stimulation in chronic tinnitus: Evaluating long term anodal exposure to left auditory cortex

#### Protocol summary

##### Summary

This double blinded clinical trial aims to investigate the therapeutic effects of auditory cortex anodal, cathodal, and sham transcranial direct current stimulation (tDCS) on chronic idiopathic tinnitus resistant to medications. Ninety patients, male and female (18 to 70 years old) with chronic drug resistant idiopathic tinnitus are randomly divided into three groups of anodal, cathodal, and sham treatments (n=30). Inclusion criteria are chronic idiopathic tinnitus for more than 6 months, resistance to medications. Exclusion criteria are history of seizure attacks, high blood pressure, pace maker, brain trauma, and severe psychiatric disorders. Anodal stimulation consists of daily one session (2 mA for 20 min with 35 cm<sup>2</sup> electrode), 5 consecutive sessions per week for two consecutive weeks (10 sessions) where anode is placed at left auditory cortex and cathode at right auditory cortex. The cathodal stimulation consists of the same protocol while anode at right auditory cortex and cathode at left auditory cortex. In the sham treatment, electrode montage is the same with anodal group, but after 40-50 sec the device will be turned OFF without informing the patients. The primary outcome is score of tinnitus handicap inventory (THI), assessed prior and post interventions (one hour after last session). The secondary outcome is tinnitus loudness and distress which are assessed using a 0 to 10 numerical rating scale prior and post each tDCS session (5 min after end of session), one week, and one month after last tDCS session. Therapeutic effects are compared inter- and intra-group.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016110124635N6**

Registration date: **2017-06-01, 1396/03/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-06-01, 1396/03/11

##### Registrant information

###### Name

Ali Yadollahpour

###### Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 61 3321 1208

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##### Recruitment status

**Recruitment complete**

##### Funding source

Ahvaz Jundishapur University of Medical Sciences (U-94187)

##### Expected recruitment start date

2016-04-29, 1395/02/10

##### Expected recruitment end date

2016-10-31, 1395/08/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Therapeutic effects of transcranial direct current stimulation in chronic tinnitus: Evaluating long term anodal exposure to left auditory cortex

##### Public title

Transcranial direct current stimulation for chronic tinnitus treatment

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: chronic tinnitus for more than 6 months; resistance to medications; idiopathic tinnitus.

Exclusion criteria: history of seizure attacks; high blood pressure; pace maker; brain trauma; severe psychiatric

## Age

From **18 years** old to **70 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **90**

## 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

Ethical Research Committee, Ahvaz Jundishapur University of Medical Sciences

##### Street address

Deputy of Research, Ahvaz Jundishapur University of Medical Sciences, Golestan Blv.

##### City

Ahvaz

##### Postal code

6135715794

#### Approval date

2016-02-10, 1394/11/21

#### Ethics committee reference number

IR.AJUMS.REC.1394.639

## Health conditions studied

### 1

#### Description of health condition studied

chronic tinnitus

#### ICD-10 code

H93.1

## ICD-10 code description

chronic tinnitus

## Primary outcomes

### 1

#### Description

Tinnitus Handicap Inventory (THI) Score

#### Timepoint

Pre intervention, Post intervention at one hour after last transcranial direct current stimulation (tDCS) session and at one month after last tDCS session.

#### Method of measurement

THI questionnaire

## Secondary outcomes

### 1

#### Description

tinnitus intensity

#### Timepoint

Prior and post each transcranial direct current stimulation (tDCS) session (5 min after end of session), one week, and one month after last tDCS session

#### Method of measurement

Numerical rating scale (0 to 10)

### 2

#### Description

Tinnitus distress

#### Timepoint

Prior and post each transcranial direct current stimulation (tDCS) session (5 min after end of session), one week, and one month after last tDCS session

#### Method of measurement

Numerical rating scale (0 to 10)

## Intervention groups

### 1

#### Description

Anodal intervention group (n=30): Treatment protocol consists of daily one session (2 mA for 20 min with 35 cm<sup>2</sup> electrode), 5 consecutive sessions per week for two consecutive weeks (10 sessions) where anode is placed at left auditory cortex and cathode at right auditory cortex.

#### Category

Treatment - Devices

### 2

#### Description

Cathodal intervention group (n=30): Treatment protocol consists of daily one session (2 mA for 20 min with 35 cm<sup>2</sup> electrode), 5 consecutive sessions per week for two consecutive weeks (10 sessions) where anode is placed at auditory cortex and cathode at left auditory cortex.

**Category**

Treatment - Devices

**3****Description**

Sham treatment (n=30): Treatment protocol is the same as anodal treatment, but after 40-50 sec the device will be turned OFF without informing the patients.

**Category**

Placebo

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

Bioelectromagnetic Clinic, Ahvaz Imam Khomeini Hospital

**Full name of responsible person**

Dr Ali Yadollahpour

**Street address**

Bioelectromagnetic Clinic, Ahvaz Imam Khomeini Hospital, Azadegan St.

**City**

Ahvaz

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

Ahvaz Jundishapur University of Medical Sciences

**Full name of responsible person**

Behzad Sharif Makhmalzadeh, PhD

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**Grant name****Grant code / Reference number**

u-94187

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

Yes

**Title of funding source**

Ahvaz Jundishapur University of Medical Sciences

**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**

Bioelectromagnetic Clinic, Ahvaz Imam Khomeini Hospital, Ahvaz Jundishapur University of Medical Sci

**Full name of responsible person**

Ali Yadollahpour

**Position**

Head of Clinic/ PhD

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

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Nader Saki

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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*