

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Clinical trial of comparison of effects of long term bifrontal anodal, cathodal, and sham treatment of transcranial direct current stimulation on tinnitus symptoms in patients with chronic idiopathic drug resistant tinnitus

Protocol summary

Summary

This double blinded clinical trial aims to investigate the therapeutic effects of bifrontal anodal, cathodal, and sham transcranial direct current stimulation (tDCS) on chronic idiopathic tinnitus resistant to medications. Seventy five 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=25). 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 cm² electrode), 5 consecutive sessions per week for two consecutive weeks (10 sessions) where anode is placed at left dorsolateral prefrontal cortex (DLPFC) and cathode at right DLPFC. The cathodal stimulation consists of the same protocol while anode at right DLPFC and cathode at left DLPFC. 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: **IRCT2016110124635N5**

Registration date: **2016-12-06, 1395/09/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-12-06, 1395/09/16

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapur University of Medical Sciences
(U-94187)

Expected recruitment start date

2016-03-01, 1394/12/11

Expected recruitment end date

2016-08-01, 1395/05/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of comparison of effects of long term bifrontal anodal, cathodal, and sham treatment of transcranial direct current stimulation on tinnitus symptoms in patients with chronic idiopathic drug resistant tinnitus

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 disorders.

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: **75**

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

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6135715794

Approval date

2016-02-13, 1394/11/24

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=25): Treatment protocol consists of daily one session (2 mA for 20 min with 35 cm² electrode), 5 consecutive sessions per week for two consecutive weeks (10 sessions) where anode is placed at left dorsolateral prefrontal cortex (DLPFC) and cathode at right DLPFC.

Category

Treatment - Devices

2**Description**

Cathodal intervention group (n=25): Treatment protocol consists of daily one session (2 mA for 20 min with 35 cm² electrode), 5 consecutive sessions per week for two consecutive weeks (10 sessions) where anode is placed at right dorsolateral prefrontal cortex (DLPFC) and cathode at left DLPFC.

Category

Treatment - Devices

3**Description**

Sham treatment (n=25): 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

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

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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**

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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