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 cm2 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

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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

2016-04-29, 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 cm2 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 cm2 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
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Bioelectromagnetic Clinic, Ahvaz Imam Khomeini Hospital, Azadegan St.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz Jundishapur University of Medical ŝciences
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 ŝciences
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
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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