# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## Investigating the effect of treatment with Cerebrum electrical stimulation on tinnitus patients with normal hearing sensitivity: A Randomized Clinical trial study

## Protocol summary

**Study aim**

Assessing the Effect of Electrical Stimulation in Patients with Chronic Tinnitus and Normal Hearing Sensitivity

**Design**

patients are randomly divided into two treatment groups and a placebo group (sham control). Each group will have 20 patients. The clinical trial has a control group, with parallel groups, randomized, on 40 patients.

**Settings and conduct**

Patients with tinnitus disease and with normal hearing sensitivity are selected for this study after hearing evaluations by audiometric specialists referring to Imam Khomeini Hospital

**Participants/Inclusion and exclusion criteria**

Tinnitus patients with normal hearing sensitivity are selected for this study after hearing diagnosis of chronic tinnitus problem. People who have contraindications for tDCS are: cardiovascular patients, pregnant women, brain patients, people with a history of brain surgery, people with metal or electronic implants, and people with a history of mental and psychological diseases.

**Intervention groups**

بیماران گروه درمانی پروتکل تابش جریان مستقیم فراقشری (tDCS) را به صورت جریان 2 میلی آمپر، مدت زمان 20 دقیقه، الکترود آند بر روی قشر (T3) و الکترود کاتد بر روی قشرشنوایی نیمکره چپ کار گذاشته می‌شود. مکان جایگذاری (T4) شنوایی نیمکره راست الکترود جریان با استفاده از استاندارد الکترودگذاری 10-20 نوار مغزی انجام می‌شود. از الکترودهای مربعی 35 سانتی متر مربع کربنی که با محلول سالین 0.9 درصد مرطوب شده تا رسانایی مطلوب برای ایجاد جریان را ایجاد کند. تابش روزانه یک بار و به مدت 10 روز انجام می‌شود (دستگاه Oasis Pro). شاخص درمانی اولیه میزان بلندی صدای وزوز و میزان آزردگی بیمار ناشی از وزوز می‌باشد. میزان بلندی ارزیابی می شود که با استفاده از VAS صدا بوسیله ی پرسشنامه مقیاس عددی رتبه‌ای 0 تا 10 تعیین می‌شود و مقادیر بزرگتر نشان دهنده ی شدت بیشتر بلندی صدای وزوز می باشد. میزان آزردگی بیمار ارزیابی می شود THI ناشی از وزوز بوسیله ی پرسشنامه ی

**Main outcome variables**

loudness and annoyance before and after treatment.

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20240503061635N1**
Registration date: **2024-07-14, 1403/04/24**
Registration timing: **prospective**

Last update: **2024-07-14, 1403/04/24**
Update count: **0**

**Registration date**

2024-07-14, 1403/04/24

**Registrant information**

**Name**

Mehdi Karimipour

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 61 3333 0074

**Email address**

karimipour.m@ajums.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2024-07-22, 1403/05/01

**Expected recruitment end date**

2025-02-19, 1403/12/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**
empty

**Scientific title**
Investigating the effect of treatment with Cerebrum electrical stimulation on tinnitus patients with normal hearing sensitivity: A Randomized Clinical trial study

**Public title**
Investigating the effect of treatment with Cerebrum electrical stimulation on tinnitus patients with normal hearing sensitivity

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Patients with tinnitus and natural hearing sensitivity are selected by ENT specialists and authentic evaluations by ENT specialists and diagnosed chronic tinnitus problems for this study. Patients with idiopathic tinnitus who have not responded to drug treatments are selected for this program. The age range is from 20 to 70 years.

**Exclusion criteria:**
Cardiovascular patients pregnant women Brain patients History of brain surgery People with metal or electronic implants People with a history of mental illness psychological People with a history of alcohol and drug abuse

**Age**
From **20 years** old to **70 years** old

**Gender**
Both

**Phase**
N/A

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **80**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
Patients with qualified criteria will be divided into two groups using random block design. Online website (https://www.seaaledenvelope.com) is used to generate a random list based on the desired sample size and block size 4. After creating a list, each patient will be identified with a unique code during the study. 20 people are selected for the intervention group and 20 are selected for the Sham Group.

**Blinding (investigator's opinion)**
Not blinded

**Blinding description**

**Placebo**
Not used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Ethics Committee of Jundishapur University of Medical Sciences

**Street address**
Iran - Ahvaz - Golestan Boulevard - Jundishapur University

**City**
Ahwaz

**Province**
Khouzestan

**Postal code**
1579461357

**Approval date**
2024-07-02, 1403/04/12

**Ethics committee reference number**
IR.AJUMS.REC.1403.148

## Health conditions studied

### 1

**Description of health condition studied**
Tinnitus - the beauty of hearing

**ICD-10 code**
H93.1

**ICD-10 code description**
Tinnitus

## Primary outcomes

### 1

**Description**
loudness level of tinnitus

**Timepoint**
10 DAYS

**Method of measurement**
Transcortical direct current (tDCS) irradiation at a current of 2 mA

## Secondary outcomes

### 1

**Description**
The degree of patient annoyance caused by tinnitus by THI questionnaire

**Timepoint**
10 DAYS

**Method of measurement**
THI questionnaire

## Intervention groups

**1**

**Description**

Each group will have 20 patients. The patients of the treatment group received transcortical direct current radiation protocol (tDCS) in the form of a current of 2 mA, a duration of 20 minutes, the anode electrode was placed on the auditory cortex of the left hemisphere (T3) and the cathode electrode was applied on the auditory cortex of the right hemisphere (T4). Placement of the current electrode is performed using the standard electrode placement of 10-20 EEG. of 35 cm2 square carbon electrodes moistened with 0.9% saline solution to create the desired conductivity for generating current. Irradiation is done once a day for 10 days (Oasis Pro device). The primary therapeutic index is the loudness of the tinnitus and the patient's annoyance caused by the tinnitus. The loudness of the voice is evaluated by the VAS questionnaire, which is determined using a numerical scale of 0 to 10, and the larger values indicate the greater intensity of the loudness of the buzzing sound. The degree of annoyance of the patient caused by tinnitus is evaluated by the THI questionnaire, which consists of 25 questions and each question is answered as yes/no and sometimes, and scores of 4, 0, and 2 are given to each answer, respectively. Scores between 0-100 are obtained and higher values indicate higher intensity of irritation caused by tinnitus. The loudness of tinnitus and its annoyance are measured before the beginning of the treatment sessions and one week and two weeks after the end of the treatment sessions and are compared for each patient. Also, the difference between these values between the active treatment group and the placebo group (sham control) is also compared.

**Category**

Treatment - Devices

**2**

**Description**

Control group: Control group: In the patients of the control group, the electrode is connected, but no electrical stimulation is applied and it only has a psychological aspect.

**Category**

Placebo

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Specialized Clinic of Imam Khomeini Hospital

**Full name of responsible person**
Nader Saki

**Street address**
Azadegan Street, Ahvaz, Khuzestan Province

**City**
Ahvaz

**Province**
Khouzestan

**Postal code**
۶۱۹۳۶۷۳۱۶۶

**Phone**
+98 61 3222 2922

**Email**
Mehdi.karimipour88@gmail.com

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Ahvaz University of Medical Sciences

**Full name of responsible person**
Nader saki

**Street address**
Khuzestan Province, Ahvaz, Boulevard of Medical Sciences, 7MW2+W4Q

**City**
Ahvaz

**Province**
Khouzestan

**Postal code**
6135733111

**Phone**
+98 61 3333 0020

**Email**
info@ajums.ac.ir

**Grant name**
Jundishapur University Research Assistant

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**
No

**Title of funding source**
Jundishapur University of Ahvaz

**Proportion provided by this source**
100

**Public or private sector**
Public

**Domestic or foreign origin**
Domestic

**Category of foreign source of funding**
*empty*

**Country of origin**

**Type of organization providing the funding**
Academic

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**
Ahvaz University of Medical Sciences

**Full name of responsible person**
Nader saki

**Position**
Assistant Professor

**Latest degree**
Specialist

**Other areas of specialty/work**
Ear, Nose, and Throat

**Street address**
The Jundishapur University of Medical Sciences is located in the cJundishapur University of Medical Sciences Golestan Boulevard, University City Ahvaz, Khuzestan Province Iran
**City**
Ahvaz
**Province**
Khouzestan
**Postal code**
15794- 61357a
**Phone**
+98 61 3314 0000
**Email**
saki-n@ajums.ac.ir

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Ahvaz University of Medical Sciences
**Full name of responsible person**
Nader saki
**Position**
Associate professor
**Latest degree**
Specialist
**Other areas of specialty/work**
Ear, Nose, and Throat
**Street address**
اهواز ، بلوار علوم پزشکی ، علوم پزشکی جندی شاپور
**City**
Ahvaz
**Province**
Khouzestan
**Postal code**
6135715794
**Phone**
+98 61 3314 0000
**Email**
saki-n@ajums.ac.ir

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Ahvaz University of Medical Sciences
**Full name of responsible person**
Nader Saki
**Position**
Associate professor
**Latest degree**
Specialist
**Other areas of specialty/work**
Ear, Nose, and Throat
**Street address**
Ahvaz - Boulevard of Medical Sciences - Jundishapur Medical Sciences
**City**
Ahvaz
**Province**
Khouzestan
**Postal code**
61365715794
**Phone**
+98 61 3314 0000
**Email**
saki-n@ajums.ac.ir

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Undecided - It is not yet known if there will be a plan to make this available
**Study Protocol**
Undecided - It is not yet known if there will be a plan to make this available
**Statistical Analysis Plan**
Not applicable
**Informed Consent Form**
Undecided - It is not yet known if there will be a plan to make this available
**Clinical Study Report**
Undecided - It is not yet known if there will be a plan to make this available
**Analytic Code**
Undecided - It is not yet known if there will be a plan to make this available
**Data Dictionary**
Undecided - It is not yet known if there will be a plan to make this available