

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

The evaluation of effects of electrical stimulation in treatment of patients with chronic tinnitus with normal hearing sensitivity

Protocol summary

Study aim

The evaluation of effects of electrical stimulation in treatment of patients with chronic tinnitus with normal hearing sensitivity

Design

The clinical trial has an intervention and control group on 40 patients who have been randomized by random allocation method.

Settings and conduct

Patients referred to Tabassom specialized clinic who meet the inclusion criteria will randomly divided into two groups of intervention and control. The intervention group will receive the Transcranial Direct-Current Stimulation radiation (tDCS) protocol in the form of 2 mA current for 20 minutes, while the anode electrode was placed on the left hemisphere cortex (T3) and the cathode electrode was placed on the right hemisphere cortex (T4). The location of the current electrode was determined using the 10-20 electrode electrode standard. 35 cm² square carbon electrodes moistened with 0.9% saline solution will be used to create the desired conductivity to create current. Irradiation was performed by Oasis pro once a day for 10 days.

Participants/Inclusion and exclusion criteria

People with normal hearing level who suffers from idiopathic tinnitus for at least 3 months and has not responded to medical drugs, will be chosen.

Intervention groups

Patients in the intervention group receive a very weak direct electric current which enters the brain from specific points of the skull and affects the areas involved in tinnitus. The control group will continue the routine medical therapy.

Main outcome variables

Tinnitus loudness according to visual analogue scale rating; Tinnitus handicap scale according to Tinnitus Handicap Inventory Questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210429051130N1**

Registration date: **2021-05-28, 1400/03/07**

Registration timing: **registered_while_recruiting**

Last update: **2021-05-28, 1400/03/07**

Update count: **0**

Registration date

2021-05-28, 1400/03/07

Registrant information

Name

Seyyed Mohammad Tabibzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 9367 3111

Email address

tabibzadeh.sm@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-22, 1400/03/01

Expected recruitment end date

2021-07-23, 1400/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The evaluation of effects of electrical stimulation in treatment of patients with chronic tinnitus with normal hearing sensitivity

Public title
The effect of electrical stimulation on tinnitus

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Tinnitus lasting at least for 3 months. Idiopathic tinnitus
Normal hearing threshold
Exclusion criteria:
History of neck disorders Psychological disorders Brain injury Epilepsy

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Random assignment of patients to intervention and control groups by lot. For this purpose, we prepare two sheets and write "Intervention 1" on one and "Intervention 2" on the other. Then, with each patient's visit, one of the sheets is randomly chosen and the patient is assigned to intervention group 1 or intervention 2.

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 Ahvaz Jundishapur University of Medical Sciences

Street address

24 Metri Ave, Imam Khomeini hospital, Ahwaz city

City

Ahwaz

Province

Khouzestan

Postal code

6193673111

Approval date

2021-04-15, 1400/01/26

Ethics committee reference number

IR.AJUMS.HGOLESTAN.REC.1400.010

Health conditions studied

1

Description of health condition studied

Tinnitus

ICD-10 code

H93.1

ICD-10 code description

Tinnitus

Primary outcomes

1

Description

Tinnitus loudness according to visual analogue scale rating

Timepoint

Before intervention, 7 and 14 days after intervention

Method of measurement

Visual Analogue Scale Questionnaire

2

Description

Tinnitus handicap scale according to Tinnitus Handicap Inventory Questionnaire

Timepoint

Before intervention, 7 and 14 days after intervention

Method of measurement

Tinnitus Handicap Inventory Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in the therapy group will apply the Transcranial direct-current stimulation (tDCS) radiation protocol at 2 mA for 20 minutes while the anode electrode will be applied to the left hemisphere cortex (T3) and the cathode electrode will be applied to the right hemisphere cortex (T4). The placement location of the current electrode will be determined using the 10-20 electrode electrode standard. 35 cm² square carbon electrodes moistened with 0.9% saline solution will be used to create the desired conductivity to create the current. Irradiation will be performed by Oasis pro device once a day for 10 days.

Category

Treatment - Other

2

Description

Control group: In the sham tDCS (control) group, the electrode montage will be the same as for the intervention group, but the device will be turned off after 30 seconds without the participant's knowledge.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

ENT Clinic, Imam Khomeini Hospital, Ahvaz, Iran

Full name of responsible person

Soheila Nikakhlagh

Street address

ENT Clinic, Imam Khomeini Hospital, Ahvaz, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Soheila Nikakhlagh

Street address

Golestan Ave, Ahwaz university of medical science

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz University of Medical Sciences

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

Seyyed Mohammad Tabibzadeh

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Ear, Nose, and Throat

Street address

24 Metri Ave, Imam Khomeini hospital, ENT department, Ahwaz city

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Soheila Nikakhlagh

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

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Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Ear, Nose, and Throat

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is 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

Title and more details about the data/document

All statistical files and questionnaires are accessible (names are coded)

When the data will become available and for how long

After publication to

To whom data/document is available

Researchers in the field of tinnitus rehabilitation

Under which criteria data/document could be used

For research and treatment purposes

From where data/document is obtainable

Hearing research center, Ahvaz Jundishapur University of Medical Sciences

What processes are involved for a request to access data/document

1- Send your request to Ahvaz Jundishapur University of Medical Sciences, AFTER APPROVAL 2- Hearing research center

Comments