

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Effect of dual intervention based on physiological inhibition (auditory Stroop) and transcranial direct current stimulation on tinnitus control: a randomized clinical trial

Protocol summary

Study aim

To assess the effect of dual intervention based on physiological inhibition (auditory Stroop) and transcranial direct current stimulation on tinnitus control

Design

This is a randomized clinical trial, phase II, in which 17 eligible patients will be randomly assigned to the intervention 1 and intervention 2 groups.

Settings and conduct

The eligible patients with chronic tinnitus referring to the Audiology Clinic in Tehran city during the study period will be enrolled in the trial and will be randomly assigned to the intervention 1 and intervention 2 groups through the drawing of lots.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 70 years, Non-pulsatile tinnitus for more than 6 months, Being right-handed, Exclusion criteria: Hyperoccosis, Use of hearing aids, Psychological disorders, Active diseases of the ear and nervous system

Intervention groups

Intervention group 1: Transcranial direct current stimulation (tDCS) 20 min each time at daily intervals for 6 sessions and then physiological inhibition (auditory Stroop) one hour each time at daily intervals for 8 sessions Intervention group 2: Transcranial direct current stimulation (tDCS) Sham technic 20 min each time at daily intervals for 6 sessions and then physiological inhibition (auditory Stroop) one hour each time at daily intervals for 8 sessions

Main outcome variables

Primary outcome: Tinnitus length, tinnitus annoyance, tinnitus handicap

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N366**

Registration date: **2020-09-17, 1399/06/27**

Registration timing: **prospective**

Last update: **2020-09-17, 1399/06/27**

Update count: **0**

Registration date

2020-09-17, 1399/06/27

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-22, 1399/07/01

Expected recruitment end date

2021-03-15, 1399/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of dual intervention based on physiological inhibition (auditory Stroop) and transcranial direct current stimulation on tinnitus control: a randomized clinical trial

Public title

Effect of dual intervention based on physiological inhibition (auditory Stroop) and transcranial direct current stimulation on tinnitus control

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age of 18 to 70 years, Non-pulsatile tinnitus for more than 6 months, Being right handed,

Exclusion criteria:

Hyperoccosis, Use of hearing aids, Psychological disorders, Active diseases of the ear and nervous system

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: **34**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment of the patients to the intervention and control groups through the drawing of lots. To do this, we prepare two sheets and write "intervention 1" on one sheet and "intervention 2" on another. Then, by referring each patient, one of the sheets will be randomly taken and the patient will be assigned to the intervention 1 or intervention 2 groups.

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 the School of Medicine - Iran University of Medical Sciences

Street address

Hemat Highway, beside Milad Tower, Iran University

of Medical Sciences, School of Medicine

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2020-07-27, 1399/05/06

Ethics committee reference number

IR.IUMS.FMD.REC.1399.379

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 length

Timepoint

Before intervention and after the sixth and eighth sessions

Method of measurement

Based on psychoacoustic assessment

2**Description**

Tinnitus annoyance

Timepoint

Before intervention and after the sixth and eighth sessions

Method of measurement

Using visual analog scale (VAS)

3**Description**

Tinnitus handicap

Timepoint

Before the intervention and after the sixth and eighth sessions

Method of measurement

Using the Tinnitus Handicap Inventory (THI) questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Transcranial direct current stimulation (tDCS) 20 min each time at daily intervals for 6 sessions and then physiological inhibition (auditory stroop) one hour each time at daily intervals for 8 sessions

Category

Treatment - Other

2

Description

Intervention group 2: Transcranial direct current stimulation (tDCS) Sham technic 20 min each time at daily intervals for 6 sessions and then physiological inhibition (auditory stroop) one hour each time at daily intervals for 8 sessions

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Audiology Clinic in Tehran city

Full name of responsible person

Maryam Emadi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Iran 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

Hamedan University of Medical Sciences

Full name of responsible person

Maryam Emadi

Position

Rehabilitation Student

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

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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

Undecided - It is not yet known if there will be a plan to make this available

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