Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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)

Phone
+98 81 1838 0090

Email address
poorolajal@umsha.ac.ir

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
Street address
Clinic of Audiology, School of Rehabilitation, Mohseni Squ.
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 8670 2503
Email
maryamemadi1396@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr. Abbas Motevalian
Street address
Hemat Highway, beside Milad Tower, Iran University of Medical Sciences
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 8670 2503
Email
research-m@ums.ac.ir
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
Rehabilitation management
Street address
School of Rehabilitation, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3838 0572
Email
maryamemadi1396@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr. Mehdi Akbari
Position

Audiologist
Latest degree
Ph.D.
Other areas of specialty/work
Audiology
Street address
Department of Audiology, School of Rehabilitation, Mohseni Squ.
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 8670 2503
Email
akbari.ums@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Dr. Jalal Poorolajal
Position
Professor of Epidemiology
Latest degree
Ph.D.
Other areas of specialty/work
Epidemiology
Street address
School of Public Health, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3838 0090
Email
poorolajal@umsha.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
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