Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effect of using simultaneous transcranial random noise stimulation with and without sound therapy on tinnitus: a randomized clinical trial

Protocol summary

Study aim
To assess the effect of using simultaneous transcranial random noise stimulation with and without sound therapy on tinnitus

Design
This is a randomized clinical trial with control group, phase III, in which eligible patients will be randomly assigned through the drawing of lots to the intervention and control groups

Settings and conduct
This study will be performed in the Besat Hospital in Hamadan city on 40 eligible patients with chronic tinnitus. The patients will be randomly assigned to the intervention and control groups through the drawing of lots. Blinding is not possible in this study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age of 18 to 70 years Chronic tinnitus for at least 6 month Exclusion criteria: History of ear surgery

Intervention groups
Intervention group: Random noise transcranial stimulation for 20 minutes with a flow rate of 2 mA twice a week for 4 weeks plus sound therapy by providing sound stimulation to both ears. Control group: Random noise transcranial stimulation for 20 minutes with a flow rate of 2 mA twice a week for 4 weeks

Main outcome variables
Primary outcome: Loudness of tinnitus; tinnitus annoyance; tinnitus disability

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120215009014N462**
Registration date: **2023-02-15, 1401/11/26**
Registration timing: **prospective**
Last update: **2023-02-15, 1401/11/26**
Update count: **0**

Registration date
2023-02-15, 1401/11/26

Registrant information

Name
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Name of organization / entity
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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-03-06, 1401/12/15

Expected recruitment end date
2023-12-06, 1402/09/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of using simultaneous transcranial random noise stimulation with and without sound therapy on tinnitus: a randomized clinical trial

Public title
Effect of using simultaneous transcranial random noise stimulation with and without sound therapy on tinnitus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 18 to 70 years Chronic tinnitus for at least 6 month

Exclusion criteria:

History of ear surgery

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **40**

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" on one sheet and "control" on another. Then, by referring each patient, one of the sheets will be randomly taken and the patient will be assigned to the intervention or control 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 Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

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Hamadan

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6517838695

Approval date

2023-02-07, 1401/11/18

Ethics committee reference number

IR.UMSHA.REC.1401.982

Health conditions studied

1

Description of health condition studied

Tinnitus

ICD-10 code

H93.1

ICD-10 code description

Tinnitus

Primary outcomes

1

Description

Loudness of tinnitus

Timepoint

Before the intervention and immediately after the intervention as well as two weeks and one month later

Method of measurement

using an audiometer

2

Description

Tinnitus annoyance

Timepoint

Before the intervention and immediately after the intervention as well as two weeks and one month later

Method of measurement

Using Visual Analog Scale (VAS)

3

Description

Tinnitus disability

Timepoint

Before the intervention and immediately after the intervention as well as two weeks and one month later

Method of measurement

Using the Tinnitus Handicap Inventory (THI)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Random noise transcranial stimulation for 20 minutes with a flow rate of 2 mA twice a week for 4 weeks plus sound therapy by providing sound stimulation to both ears.

Category

Treatment - Other

2

Description

Control group: Random noise transcranial stimulation for 20 minutes with a flow rate of 2 mA twice a week for 4 weeks

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital in Hamadan city

Full name of responsible person

Dr Maryam Emadi

Street address

Besat Hospital, Shahed Square

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Province

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

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

Hamedan 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

Dr Maryam Emadi

Position

Audiologist

Latest degree

Ph.D.

Other areas of specialty/work

Audiology

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Latest degree

Ph.D.

Other areas of specialty/work

Audiology

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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