Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Sep 2026

The effect of acupuncture on the intensity of sounds heard and quality of life in patients with chronic non-pulsating tinnitus

Protocol summary

Study aim
The effect of acupuncture on the recovery and treatment of patients with chronic non-pulsating titinus

Design
Patients receive 10 sessions of acupuncture (3 times a week). Acupuncture is performed by an acupuncturist (B.N.) in specific areas. The needles used were filament types with very fine and flexible filaments. The size of the metal needle is 40 by 25 mm. The needles are placed vertically without anesthesia.

Settings and conduct
In this study, a double-blind clinical trial will be performed in the ENT department of Ghaem and Imam Reza hospitals. Eligible individuals (inclusion criteria) include patients 40 to 65 years of age with normal hearing or mild hearing loss (dB 40 SRT <) who suffer from chronic titinus (at least 6 months) on one or both sides.

Participants/Inclusion and exclusion criteria
People with chronic non-pulsating tinnitus (more than 6 months) who go to the ENT clinic of Imam Reza and Ghaem hospitals and have normal hearing or srt less than 40 DB are included in the study. Inclusion criteria include pulmonary tinnitus, having titinus with Meniere's disease and other types of dizziness, vestibular schwannoma, otosclerosis, conductive hearing loss, pregnancy, and mental disorders that make it difficult for the patient to answer the questionnaire.

Intervention groups
Patients receive 10 sessions of acupuncture (3 times a week). In the control group, people are treated with acupuncture points without the effect of tinnitus using placebo needles. These placebo needles do not penetrate the skin and are completely painless and harmless. The position of patients and the preparation process are similar in both groups. At the beginning and end of the treatment period, all patients complete the THI questionnaire.

Main outcome variables
Tinnitus volume

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210411050928N1**
Registration date: **2021-05-02, 1400/02/12**
Registration timing: **registered_while_recruiting**

Last update: **2021-05-02, 1400/02/12**
Update count: **0**

Registration date
2021-05-02, 1400/02/12

Registrant information

Name
Afsaneh Mohammadpoormaleki

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
2021-04-11, 1400/01/22

Expected recruitment end date
2021-07-21, 1400/04/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The effect of acupuncture on the intensity of sounds heard and quality of life in patients with chronic non-pulsating tinnitus

Public title
The effect of acupuncture on the intensity of sounds heard and quality of life in patients with chronic non-pulsating tinnitus

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
chronic non-pulsating tinnitus

Exclusion criteria:
Pulsating tinnitus having Titinus with Meniere's disease and other types of vertigo, vestibular schwannoma, otosclerosis, conductive hearing loss pregnancy mental disorders that make it difficult for the patient to answer the questionnaire

Age
From **40 years** old to **65 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, all eligible patients, with the help of a sequence of random numbers extracted from the computer (via the website www.randomization.com) and by simple randomization were divided into two groups of control (placebo) and intervention (acupuncture). The resulting random numbers and the fact that patients were assigned to groups were concealed with the help of sealed envelopes.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients participating in the study do not know in which intervention or control group they were placed. Patients are randomly assigned to one of the two groups of acupuncture (case) and placebo (control), using four randomly fixed blocks. The analyzer does not know the type of intervention.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of mashhad University of Medical Sciences

Street address
No. 12, Vakilabad Ave, No. 28

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Mashhad

Province
Razavi Khorasan

Postal code
9178866352

Approval date
2019-08-13, 1398/05/22

Ethics committee reference number
ir.mums.medical.rec.1399.165

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 volume

Timepoint
At the beginning of the study and after the end of the treatment period, all patients complete the THI questionnaire.

Method of measurement
Tinnitus Handicap Inventory (THI) and Visual-analogue scale (VAS) questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Appropriate acupuncture points are selected for the treatment of tinnitus, including GB2, GB20, SJ21, SI19, SJ17, SJ3, SJ5, LI4, and SI6, and

patients receive 12 sessions of acupuncture (3 times a week). Acupuncture is performed by an acupuncturist (B.N.) in specific areas. The needles used were filament types with very fine and flexible filaments. The size of the metal needle is 40 by 25 mm. The needles are placed vertically without anesthesia.

Category

Treatment - Other

2

Description

Control group: People in areas suitable for acupuncture to treat tinnitus, including GB2, GB20, SJ21, SI19, SJ17, SJ3, SJ5, LI4, and SI6, are treated with placebo needles without affecting tinnitus. These placebo needles do not penetrate the skin and are completely painless and harmless. The position of the patients and the preparation process are similar to the intervention group.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Ghaem hospital
Full name of responsible person
Afsaneh mohammadpoor maleki
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2

Recruitment center

Name of recruitment center
Emam Reza hospital
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Sponsors / Funding sources

1

Sponsor

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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

Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Afsaneh Mohammadpoor Maleki
Position
ENT Resident
Latest degree
Medical doctor
Other areas of specialty/work
Ear, Nose, and Throat
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Person responsible for scientific inquiries

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Person responsible for updating data

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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