

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 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 tinnitus

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 tinnitus (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 tinnitus 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

Country

Iran (Islamic Republic of)

Phone

+98 51 3891 0728

Email address

mohammadpoura961@mums.ac.ir

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

City

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

Street address

Ahmadabad Ave

City

Mashhad

Province

Razavi Khorasan

Postal code

9176999311

Phone

+98 51 3841 3492

Email

mohammadpoura961@mums.ac.ir

2

Recruitment center

Name of recruitment center

Emam Reza hospital

Full name of responsible person

Afsane Mohammadpoor Maleki

Street address

Ebnesima Ave

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3854 3031

Email

IRH.CRU@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsan Tafaghodi Piade Gheibi

Street address

Ghoreishi Building, Daneshgah Ave.

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3841 1538

Email

vcresraech@mums.ac.ir

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

Street address

No. 12 , Vakilabad Ave, No 28.

City

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Province

Razavi Khorasan

Postal code

9178866352

Phone

+98 51 3891 0728

Email

mohammadpoura961@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Afsaneeh Mohammadpoor Maleki

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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City

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Razavi Khorasan

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9176999311

Phone

+98 51 3841 3492

Email

mohammadpoura961@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Afsaneeh Mohammadpoor Maleki

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Ear, Nose, and Throat

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Phone

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Email

mohammadpoura961@mums.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