Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Comparing of Gabapentin and Cinnarizine Effect on Tinnitus in Patients with Sensorineural Hearing Loss

Protocol summary

Study aim
Comparing of Gabapentin and Cinnarizine effect on tinnitus in patients with Sensorineural Hearing Loss and Ability to provide a safe, non-invasive, effective and economical treatment for patients with Tinnitus

Design
Two arm parallel group randomized trial with 114 patients, Randomization with a table of random numbers on an online site

Settings and conduct
114 patients who referred to the ENT clinic of Imam Khomeini Hospital in Urmia with a complaint of Tinnitus and have sensorineural hearing loss and have entry condition and do not have the non-entry condition of the study after completing the consent form by the patients for participation In this study, taking a complete history and performing examinations, and if needed, performing audiometry and necessary tests, the THI questionnaire will be completed for them. Patients are randomly divided into two groups, A and B (A: Gabapentin, B: Cinnarizine), and are treated for 6 weeks, and after the completion of the treatment period, they return to complete the THI questionnaire.

Participants/Inclusion and exclusion criteria
Entry condition: Age:18-75 years old, Having persistent and pulseless Tinnitus for at least one year, Having Sensorineural Hearing Loss, Obtaining a score of 38 and above in the Tinnitus Handicap Inventory (THI) questionnaire, Non-entry condition: Having an active Meniere's disease, Being pregnant or breastfeeding, Having any one of the following: Glaucoma, Urinary Retention, Prostatic Hypertrophy, Epilepsy, and Liver disease, Having a health condition that prohibits the use of gabapentin for the patient and other contraindications

Intervention groups
A: Gabapentin 100mg/d 1st week, 300mg/d 2nd week, 900mg/d 3rd and 4th weeks, 300mg/d 5th week, 100mg/d 6th week B: Cinnarizine 25mg/d 1st week, 50mg/d 2nd week, 75mg/d 3rd and 4th weeks, 50mg/d 5th week, 25mg/d 6th week

Main outcome variables
Tinnitus severity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221002056073N1**
Registration date: **2022-10-09, 1401/07/17**
Registration timing: **prospective**

Last update: **2022-10-09, 1401/07/17**
Update count: **0**

Registration date
2022-10-09, 1401/07/17

Registrant information

Name
Reza Samarei

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 44 3345 7286

Email address
samareireza@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-10-23, 1401/08/01

Expected recruitment end date
2023-02-19, 1401/11/30

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing of Gabapentin and Cinnarizine Effect on Tinnitus in Patients with Sensorineural Hearing Loss

Public title

Comparing of Gabapentin and Cinnarizine Effect on Tinnitus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The patient has continuous tinnitus without pulsation for at least one year. Having sensorineural hearing loss Based on the Tinnitus Handicap Inventory (THI), the patient must have scored 38 or higher.

Exclusion criteria:

Having active Meniere's Disease Having Kidney Dysfunction Being pregnant or breastfeeding Having any of the following: Glaucoma, Urinary Retention, Prostate Hypertrophy, Epilepsy and Liver Disease Having a health condition that prohibits the use of Gabapentin for the patient or other Contraindications

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **114**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be grouped into two groups, A and B, where group A will receive Gabapentin and group B will receive Cinnarizine. In this way, the number between 1 and 114 will be applied to the patients in the order of entering the study, and then using the website https://www.graphpad.com/quickcalcs, a table of random numbers with two groups will be randomized online. We will create A and B with 57 numbers in each group from numbers 1 to 114.

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

Research Ethics Committees of Urmia University of Medical Sciences - Imam Khomeini University Hospit

Street address

Imam Khomeini University Hospital, Ershad Ave., Modarres Blvd.

City

Urmia

Province

West Azarbaijan

Postal code

5715781351

Approval date

2022-02-09, 1400/11/20

Ethics committee reference number

IR.UMSU.HIMAM.REC.1401.015

Health conditions studied

1

Description of health condition studied

Tinnitus

ICD-10 code

H93.1

ICD-10 code description

Tinnitus

Primary outcomes

1

Description

Severity of tinnitus

Timepoint

At the beginning of the study (before the start of the intervention) and 6 weeks after starting the medication

Method of measurement

Tinnitus Handicap Inventory Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Cap Gabapentin 100mg/d 1st week, 300mg/d 2nd week (100mg q8h), 900mg/d 3th and 4th weeks (300mg q8h), 300mg/d 5th week (100mg q8h), 100mg/d 6th week- oral administration

Category

Treatment - Drugs

2

Description
Control group: Tab Cinnarizine 25mg/d 1st week, 50mg/d 2nd week (25mg q12h), 75mg/d 3th and 4th weeks (25mg q8h), 50mg/d 5th week (25mg q12h), 25mg/d 6th week- oral administration
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini University Hospital
Full name of responsible person
Reza Samarei
Street address
Imam Khomeini University Hospital, Ershad Ave., Modarres Blvd.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Saber Gholizadeh
Street address
Research and Technology Vice-Chancellor Building, Headquarters of Urmia University of Medical Sciences, Emergency St., Resalat Blvd.
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5714783734
Phone
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Email
saber@umsu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Oroumia 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
Oroumia University of Medical Sciences
Full name of responsible person
Reza Samarei
Position
Associate professor
Latest degree
Specialist
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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Name of organization / entity

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Full name of responsible person

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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