

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of the efficacy of gabapentin with placebo on Idiopathic tinnitus

Protocol summary

Study aim

Assessment and comparison of recovery rate, incidence of complications, and satisfaction rate in patients received gabapentin or placebo referred to Al-Zahra Hospital Ear, Nose and Throat Clinic in 2020-2021 based on TSI questionnaire

Design

Completely randomized Clinical trial with control group, double-blind on 56 patients.

Settings and conduct

This trial will be performed as a randomized double blind placebo control design from 1398 to 1399. The subjects included all patients with idiopathic tinnitus referred to the Ear, Nose and Throat Clinic of Al-Zahra Hospital in 1998-99, who were followed up monthly for 12 weeks after the intervention.

Participants/Inclusion and exclusion criteria

All the patient with idiopathic tinnitus referred to the ENT clinic of the Al-Zahra hospital Age between 18 and 65 Satisfaction of entering the study Patient assistance to use the drug No pregnancy , lactescent, or design to pregnancy in the next 6 months Normal audiometry test Use narcotic or alcohol or sedative drugs in the past 48 hours Use MAOI, SSRI, TCA ,phenothiazine, soporific drugs in the past Sensitivity to gabapentine No satisfaction of being a case study in this study No assistance to use the drug Patient with pulsative tinnitus Patient with acute / choronic internal or middle ear infection Patient with thyroid disease Patient with rheumatologic disease Deals with noisy workplace Age more than 65 years Simultaneous use of other drugs except for gabapentin

Intervention groups

In this study, participants will receive two interventions of gabapentin and placebo. Groups A or B of participants will be treated with gabapentin (300 mg daily) or placebo for 12 weeks.

Main outcome variables

Tinitus score in tinnitus severity index questionnaire;

visual analogue scale; satisfaction rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200127046283N1**

Registration date: **2020-06-10, 1399/03/21**

Registration timing: **prospective**

Last update: **2020-06-10, 1399/03/21**

Update count: **0**

Registration date

2020-06-10, 1399/03/21

Registrant information

Name

Mohsen Rashidi ravari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3341 4754

Email address

rashidi.sd@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-22, 1399/04/02

Expected recruitment end date

2021-04-19, 1400/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	
Scientific title	Comparison of the efficacy of gabapentin with placebo on Idiopathic tinnitus
Public title	The efficacy of gabapentin on tinnitus
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criteria: All the patient with idiopathic tinnitus referred to the ENT clinic of the Al-Zahra hospital Age between 18 and 65 Satisfaction to enter this study Patient assistance to use the drug No pregnancy , lactescent, or plan to pregnancy in the next 6 months Normal audiometry test Exclusion criteria: Use narcotic or alcohol or sedative drugs in the past 48 hours Use MAOI, SSRI, TCA ,phenothiazine, soporific drugs in the past Sensitivity to gabapentine No satisfaction with being a case study in this study No assistance to use the drug Patient with pulsative tinnitus Patient with acute / choronic internal or middle ear infection Patient with thyroid disease Patient with rheumatologic disease Deals with noisy workplace Age more than 65 years Simultaneous use of other drugs except for gabapentin
Age	From 18 years old to 65 years old
Gender	Both
Phase	3
Groups that have been masked	• Participant • Investigator • Outcome assessor • Data analyser • Data and Safety Monitoring Board
Sample size	Target sample size: 56
Randomization (investigator's opinion)	Randomized
Randomization description	Method of randomization: simple Unit of randomization: individual Tools used in randomization: table of random numbers. patient assignment in groups A and B will be done based on a completely randomized design. To prevent bias in our study a double-blind design will be performed. Both analgesics are in separate boxes A and B, and only the ENT specialist is aware of the drug's content in each group.
Blinding (investigator's opinion)	Double blinded
Blinding description	Patients will be treated with prescribed medication packages by an ENT specialist. Drug packages are quite similar in shape, and the patient and project manager are unaware of the contents of the packages. Data gathering, patient analysis and filling the forms will be

done by investigator and the assistant who are not aware of the contents of the packages; In the data analysis step, the analysis will be done by the project advisor and the investigator, who are not aware of the contents of the drug packages, and groups of patients (groups 1 or 2) will be defined for the data analysis. Therefore, the study is a double blind study and from the stage of the patient's entry into the study to the study phase, data collection and data analysis, the contents of the two drug groups are not clear.	
Placebo	Used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	
1	
Ethics committee	
Name of ethics committee	Ethics committee of zahedan university of medical sciences
Street address	Alzahra Hospital; Motahari Blvd; Zahedan Town
City	Zahedan
Province	Sistan-va-Balouchestan
Postal code	9816737789
Approval date	2020-01-05, 1398/10/15
Ethics committee reference number	IR.ZAUMS.REC.1398.377
Health conditions studied	
1	
Description of health condition studied	Idiopathic tinnitus
ICD-10 code	H93.1
ICD-10 code description	Tinnitus
Primary outcomes	
1	
Description	the score of tinnitus in tinnitus severity index questionnaire and visual analogue scale
Timepoint	The amount of tinnitus at the beginning of the study and 1, 2 and 3 months after starting the drug and placebo

will be measured.

Method of measurement

Tinnitus severity index questionnaire, visual analogue scale and 5 point scale for satisfaction

Secondary outcomes

1

Description

Side effects of prescribed drug

Timepoint

1-2-3 months after using drug

Method of measurement

ask about vertigo, nausea, drowsiness, blurred vision, fatigue

Intervention groups

1

Description

Intervention group: The treated individuals included all patients with idiopathic tinnitus referred to the ETN Clinic of Al-Zahra Hospital in 1998-99, for 12 weeks after the intervention with gabapentin (300 mg daily, made by Razak Company, Tehran, Iran). They are followed up on a monthly basis. The group will be treated for 12 weeks.

Category

Treatment - Drugs

2

Description

Control group: Control individuals included all patients with idiopathic tinnitus referred to the ETN Clinic of Al-Zahra Hospital in 1998-99, which were followed up monthly for 12 weeks after the intervention with placebo. The group will also be reviewed for 12 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

the ENT clinic of Alzahra hospital in Zahedan

Full name of responsible person

Mohsen Rashidi Ravari

Street address

Motahari Blvd. before Khatam square, Zahedan Town

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Prof. Nourmohammad Bakhshani

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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

Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Mohsen Rashidi ravari

Position

Assistant 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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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All un-deidentified data will be shared once collecting.

When the data will become available and for how long

Starting one year after publication

To whom data/document is available

The outcome will be shared with academic institutes or people working in businesses

Under which criteria data/document could be used

Research Ethics Committee

From where data/document is obtainable

Raw data rashidi-darya@gmail.com

What processes are involved for a request to access data/document

Writing a request via email

Comments