Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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، nasea، drowsiness، biurred 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 ENTclinic 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

Assictant professor

Latest degree

Specialist

Other areas of specialty/work

Ear, Nose, and Throat

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rashidi.sd@gmail.com

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