

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

Tinnitus 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

##### City

Zahedan

##### Province

Sistan-va-Balouchestan

##### Postal code

9816737789

##### Phone

+98 54 3321 4157

##### Email

rashidi.sd@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Zahedan University of Medical Sciences

##### Full name of responsible person

Prof. Nourmohammad Bakhshani

##### Street address

Motahari Blvd.before Khatam square, Zahedan Town

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##### Province

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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

Assicant professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Ear, Nose, and Throat

##### Street address

Motahari Blvd; before Khatam square; Zahedan Town

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Zahra Ghiasi

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Psychiatrics

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## Person responsible for updating data

**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

**Street address**

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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**