Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Study of Single and Combination Medication Treatment of Tinnitus by Alprazolam and Fluoxetine

Protocol summary

Study aim
determine the efficacy Single and Combination Medication Treatment of Tinnitus by Alprazolam and Fluoxetine

Design
In this research, 147 patients with tinnitus referring to Amiralmomenin hospital were chosen purposefully and a code was allocated to each one of them.Then, patients were randomly divided into two control and intervention groups.

Settings and conduct
patients with chronic, non-pulsatile tinnitus (taking more than six months) will be participated in the study. An informed consent of the patients participating in the study will be obtained after giving a detailed explanation about the study. For all participants, audiometric testing will be requested before treatment and again a week after four weeks of treatment. Patients will be informed to refer to the study's designated physician in the hospital in case of fever, sore throat, rash, unusual bruising and bleeding. Patients will randomly be divided into four groups based on a random table: Group 1: Fluoxetine Group 2: Alprazolam + Fluoxetine Group 3: Placebo

Participants/Inclusion and exclusion criteria
Patients with 20-65 years of age; Tinnitus history taking at least six months; Exclusion Criteria: Acute or chronic middle ear infections; History of thyroid and rheumatologic diseases; History of occupational exposure to noise; Concomitant use of other drugs;

Intervention groups
Group 1: Fluoxetine Group 2: Alprazolam + Fluoxetine Group 3: Placebo

Main outcome variables
Tinnitus

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20080831001138N26**
Registration date: **2018-02-17, 1396/11/28**
Registration timing: **registered_while_recruiting**

Last update: **2018-02-17, 1396/11/28**
Update count: **0**

Registration date
2018-02-17, 1396/11/28

Registrant information

Name
Fataneh Bakhshi

Name of organization / entity
Guilan University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 13 1223 8307

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entrc@gums.ac.ir

Recruitment status
Recruitment complete

Funding source
Guilan University of Medical Science, Vice Chancellor for Resarch

Expected recruitment start date
2017-12-22, 1396/10/01

Expected recruitment end date
2018-12-22, 1397/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Study of Single and Combination Medication Treatment of Tinnitus by Alprazolam and Fluoxetine

Public title
Tinnitus treatment with single or combination medication
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with 20-65 years of age Tinnitus history taking at least six months
Exclusion criteria:
Acute or chronic middle ear infections History of thyroid and rheumatologic diseases History of occupational exposure to noise Concomitant use of other drugs
Age
From **20 years** old to **65 years** old
Gender
Both

Phase
4
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **147**
Randomization (investigator's opinion)
Randomized
Randomization description
According to the study's inclusion, the patients with tinnitus are assigned to tree groups by random block method. Before the study, the permutations are designed manually. 24 sextuple blocks with different permutations and a triple block of ABP are placed in a sealed envelope. Then, the blocks will be randomly taken out of the envelope, when the patients refer gradually to reach the sample size of 147. The envelopes are put in another room (research center), and a third party notifies the members about it.
Blinding (investigator's opinion)
Double blinded
Blinding description
In order to maintain double blindness in the study, both patients and all researchers will be unaware of the received drug.(A researcher will explain about the drug to the patients and record data, and another researcher will evaluate the patients). Drugs will look completely similar in shape, color and size. The patients will be divided into three groups according to the Random Number Table.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Guilan University of Medical Sciences
Street address
vice-chancellor for Research Building, opposite of Sepah Bank,Shahid Beheshti Blvd
City
Raht
Province
Guilan
Postal code
4139637459
Approval date
2017-07-29, 1396/05/07
Ethics committee reference number
IR.GUMS.REC.1395.185

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
Timepoint
Starting Time, Fifth week
Method of measurement
TSI Questionnaire and VAS Score

Secondary outcomes

1

Description
Anxiety
Timepoint
Starting Time(time0), Fifth Week
Method of measurement
Beck Anxiety Inventory (BAI)

2

Description
Depression
Timepoint
Starting Time(time0), Fifth Week

Method of measurement
Beck Depression Inventory

Intervention groups

1

Description
Alprazolam: Daily taking of 0.5 mg till the end of the fourth week of treatment
Category
Treatment - Drugs

2

Description
Oxcarbazepine: In the first week, its initial nightly dose will be 300 mg. After the second week until the end of the fourth week, the treatment will be continued with daily dose of 600 mg.
Category
Treatment - Drugs

3

Description
Fluoxetine: In the first week, its initial daily dose will be 20 mg. After the second week until the end of the fourth week, the treatment will be continued with daily dose of 50 mg.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Guilan University of Medical Sciences
Full name of responsible person
Dr Alia Saberi
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Amiralmomenin Hospital, 17 Shahrivar Ave, Emam Khomeini Ave
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rasht University of Medical Sciences
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Susan Komaee
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Shahid Beheshti Blvd.(west), opposite of Sepah Bank, vice-chancellor for Research Building, Rasht,
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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
Rasht 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
Rasht University of Medical Sciences
Full name of responsible person
Dr Alia Saberi
Position
Associate Professor
Latest degree
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Msc

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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
Not applicable

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