

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)

Phone

+98 13 1223 8307

Email address

entrc@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Guilan University of Medical Science, Vice Chancellor for Research

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 three 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
Street address
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
Full name of responsible person
Susan Komae
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Shahid Beheshti Blvd.(west), opposite of Sepah Bank, vice-chancellor for Research Building, Rasht,
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research@gums.ac.ir

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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Other areas of specialty/work
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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

Person responsible for updating data

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Fatemeh Nezamdoust

Position

Msc

Latest degree