

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

A clinical trial to compare the effect of sertraline and melatonin on the treatment of tinnitus

Protocol summary

Summary

Aim: Evaluation the effect of sertraline and melatonin on the treatment of tinnitus. Design: In this Clinical trial study, 70 patients with tinnitus will be selected according to the inclusion criteria including: tinnitus for at least 6 months; normal audiogram test; possibility of follow up; Insensitivity to sertraline, melatonin and benzodiazepine compounds and agreement to participate in this study. Patients who have tinnitus with specific etiology or have a history of recent head trauma will be excluded from the study. Afterward patients will be randomly allocated into two groups. Group 1 or intervention group receive Sertraline 50 mg tablet, once a day and group 2 or control group receive melatonin tablet 3 mg once a day for 3 months. After the end of the treatment courses, we will collect patients' outcomes' information using a questionnaire. The main outcome in this study will be tinnitus.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017011412782N13**

Registration date: **2017-03-30, 1396/01/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-03-30, 1396/01/10

Registrant information

Name

Ali Mehrabi kushki

Name of organization / entity

Isfahan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Isfahan University of Medical Sciences .

Expected recruitment start date

2015-03-20, 1393/12/29

Expected recruitment end date

2017-03-20, 1395/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial to compare the effect of sertraline and melatonin on the treatment of tinnitus

Public title

Effect of sertraline and melatonin on tinnitus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: tinnitus for at least 6 months; normal audiogram test; possibility of follow up; Insensitivity to sertraline, melatonin and benzodiazepine compounds and agreement to participate in this study. Exclusion criteria: patients who have tinnitus with specific etiology or have a history of recent head trauma.

Age

No age limit

Gender

Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: 70

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
Random selection using random numbers

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences

Street address
Isfahan University of Medical sciences, Hezar Jareeb street, Isfahan, Iran

City
Isfahan

Postal code

Approval date
2015-09-23, 1394/07/01

Ethics committee reference number
IR.MUI.REC.1395.30134

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
before intervention and three months after intervention

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: patients are treated by sertraline, 50 mg oral tablet, once a day for 3 months.

Category
Treatment - Drugs

2

Description
Control group: patients are treated by Melatonin 3 mg oral tablet, once a day for 3 months.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
AL-Zahra hospital

Full name of responsible person
Dr Seyed Hamid Abtahi

Street address
Alzahra hospital, Alzahra street, Isfahan, Iran

City
Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Isfahan University of Medical Sciences

Full name of responsible person
Dr Mansour Siavash

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Isfahan University of Medical Sciences, Hezar jareeb street, Isfahan, Iran

City
Isfahan

Grant name

Grant code / Reference number
-

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Vice chancellor for research, Isfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector*empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty*

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Full name of responsible person

Dr.Mahdi Mahmoodi

Position

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Position

Responsible for research/Master of Science

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Otolaryngologist

Other areas of specialty/work**Street address**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)***empty***Study Protocol***empty***Statistical Analysis Plan***empty***Informed Consent Form***empty***Clinical Study Report***empty***Analytic Code***empty***Data Dictionary***empty*