

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

Comparative study of the efficacy of amitriptyline and melatonin in the treatment of tinnitus

Protocol summary

Study aim

Determining and comparing the effectiveness of amitriptyline and melatonin on the treatment of tinnitus

Design

A randomized, double-blinding clinical trial, with the parallel groups, Phase 2 on 60 patients

Settings and conduct

In this randomized double-blind clinical trial, 60 eligible patients referred to the neurology clinics of Kashani and Al-Zahra hospitals in Isfahan will be included in the study and will be randomly divided into two groups. Patients in the first group will be prescribed melatonin and in the second group amitriptyline. The intervention will be performed in such a way that the patient and the researcher will have no knowledge of the type of intervention and the double-blind conditions will be established. The severity of tinnitus will then be compared between the two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria included age 18 to 65, diagnosis of subjective idiopathic tinnitus, and consent to participate in the study. Exclusion criteria included a diagnosis of psychiatric problems, susceptibility to tricyclic antidepressants, night shift jobs, high blood pressure, cardiovascular disease, aspirin, and salicylate compounds, hypercholesterolemia, and hyperlipidemia, and Hyperthyroidism.

Intervention groups

Intervention group 1: In this group, 3 mg melatonin tablets every night are prescribed for 6 weeks.

Intervention group 2: In this group, amitriptyline 50 mg tablets are prescribed for 6 weeks.

Main outcome variables

Severity of tinnitus

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200825048515N48**

Registration date: **2021-12-01, 1400/09/10**

Registration timing: **prospective**

Last update: **2021-12-01, 1400/09/10**

Update count: **0**

Registration date

2021-12-01, 1400/09/10

Registrant information

Name

Asieh Maghami Mehr

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 0000 0000

Email address

asimaghami@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-22, 1400/10/01

Expected recruitment end date

2022-03-22, 1401/01/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the efficacy of amitriptyline and melatonin in the treatment of tinnitus

Public title

The efficacy of amitriptyline and melatonin in the treatment of tinnitus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Ages 18 to 65
Diagnosis of subjective idiopathic tinnitus
Satisfaction to participate in the study

Exclusion criteria:

Diagnosis of psychiatric problems
Sensitivity to tricyclic antidepressants
Engaging in night shift jobs
High blood pressure
Cardiovascular diseases
Consumption of aspirin and salicylate compounds
Hypercholesterolemia and hyperlipidemia
Hyperthyroidism

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, 60 eligible patients are randomly selected. For this, the letter A is written on 30 sheets, and the letter B is written on 30 sheets and each of them is placed in an envelope. Each patient is then asked to choose one of the envelopes. Depending on the selected envelope, the patient is assigned to one of two groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to observe blindness, the drugs are prepared in the same shape before the intervention and are coded and given to the physician. They prescribe them without knowing the type of each drug. Therefore, the patient, the patient, the person recording the clinical and baseline information of the patients as well as the statistical analyst will not be aware of the type of intervention.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Street address Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq

City

Isfahan

Province

Isfahan

Postal code

8179964167

Approval date

2021-03-11, 1399/12/21

Ethics committee reference number

IR.MUI.MED.REC.1399.1148

Health conditions studied

1

Description of health condition studied

tinnitus

ICD-10 code

H93.1

ICD-10 code description

Tinnitus

Primary outcomes

1

Description

Severity of tinnitus

Timepoint

Before and after the intervention

Method of measurement

Tinnitus handicap inventory Questionnaire (THI)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: In this group, patients will be prescribed 3 mg melatonin tablets (Jalinous Pharmaceutical Company) every night for 6 weeks.

Category

Treatment - Drugs

2

Description

Intervention group 2: In this group, patients will be prescribed amitriptyline 50 mg tablets (Jalinous

Pharmaceutical Company) every night for 6 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashani Hospital

Full name of responsible person

Ahmad Chitsaz

Street address

Neurology Department, Kashani Hospital, Kashani Street.

City

Isfahan

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8183983434

Phone

+98 31 3233 0091

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ahmadchitsaz@med.mui.ac.ir

2

Recruitment center

Name of recruitment center

Al-Zahra Hospital

Full name of responsible person

Ahmad Chitsaz

Street address

Hezar jarib Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjooy Javanmard

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Vice Chancellor for Research, School of Medicine, Hezar Jarib Street, Isfahan.

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Grant name

Grant code / Reference number

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

No

Title of funding source

Isfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Ahmad Chitsaz

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Neurology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Ahmad Chitsaz

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Bahareh Rajol

Position

Non-faculty specialist physician

Latest degree

Subspecialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available