

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the Effect of Melatonin and Valerian versus Placebo in Treatment of Tinnitus

Protocol summary

Summary

The goal of this study is evaluation of the effect of melatonin and valerian in treatment of tinnitus. Seventy-eight patients with subjective idiopathic tinnitus are enrolled in this study. All patients will undergo clinical examination along with recording pure tone audiometry, speech reception threshold and speech discrimination scores. Moreover, tinnitus matching test will be done in two parts (loudness and pitch). Then patients will be asked to fill out Pittsburgh sleep quality and tinnitus handicap inventory questionnaires. Subsequently, patients are randomly allocated into three groups taking different medications, half an hour before going to bed at nights during 30 days. Group 1: melatonin; Group 2: valerian; Group 3: placebo. After this period, tinnitus matching tests will be repeated and questionnaires will be filled again for comparison and evaluating the changes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016011825083N3**

Registration date: **2016-06-10, 1395/03/21**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-06-10, 1395/03/21

Registrant information

Name

Farhad Farahani

Name of organization / entity

Hamedan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Research deputy of Hamedan University of Medical Sciences

Expected recruitment start date

2016-03-05, 1394/12/15

Expected recruitment end date

2017-03-05, 1395/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Effect of Melatonin and Valerian versus Placebo in Treatment of Tinnitus

Public title

Evaluation of the Effect of Melatonin and Valerian in Treatment of Tinnitus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Unilateral or Bilateral Tinnitus in 18-65 years old patients Exclusion criteria: Acute or chronic otitis media; Unilateral sensory neural hearing loss with abnormal MRI; Conductive hearing loss; Treatment with anticonvulsant and sedative drugs; Addiction; objective tinnitus; Heart disease; Mixed hearing loss

Age

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

Gender

Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 78

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Hamedan University of Medical Sciences

Street address
Ayatollah Motheri Blvd., Resalat Square

City
Hamedan

Postal code
6517838678

Approval date
2015-06-20, 1394/03/30

Ethics committee reference number
IR.umsha.Rec.1394.141

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
One month after treatment

Method of measurement

Tinnitus handicap inventory questionnaire

Secondary outcomes

1

Description
Improvement of sleep

Timepoint
One month after treatment

Method of measurement
Pittsburgh sleep questionnaire

Intervention groups

1

Description
Group 1: Treatment with melatonin 3mg, 30 minutes before sleep for one month

Category
Treatment - Drugs

2

Description
group2: Treatment with valerian 320 mg,30 minutes before sleep for one month

Category
Treatment - Drugs

3

Description
Group 3: Treatment with placebo,30 minutes before sleep for one month

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Hamedan Besat Hospital

Full name of responsible person
Dr Zahra Abbasi

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Ayatollah Motahari Blvd, Resalat Square

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Hamedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Deputy of Research and Technology of Hamedan University Medical Sciences

Full name of responsible person

Dr Bashirian

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University of Medical Sciences, Front of the Mardom
Garden, Shahid Fahmide Street

City

Hamedan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding source

Deputy of Research and Technology of Hamedan
University 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

Person responsible for general inquiries**Contact****Name of organization / entity**

Hamedan University Of Medical Sciences

Full name of responsible person

Zahra Abbasi

Position

Resident of otolaryngology and Head and Neck
Surgery

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Web page address**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