Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

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

Protocol summary

Summary

The goal of this study is evaluation of the effect of melatonin and valerian in treatment of tinitus. Seventy-eight patients with subjective idiopathic tinitus are enrolled in this study. All patients will undergo clinical examination along with recording pure tone audimeterey, speech reception threshold and speech discrimination scores . Moreover, tinitus matching test will be done in two parts (loudness and pitch). Then patients will be asked to fill out Pitsburg sleep quality and tinitus handicap inventory questionares. 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, tinitus 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

Country

Iran (Islamic Republic of)

Phone

+98 81 3252 8052

Email address

farahani@umsha.ac.ir

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 Tinitus

Public title

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

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Unilateral or Bilateral Tinitus 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 tinitus; 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
Tinitus
ICD-10 code
H93.1
ICD-10 code description
Tinitus

Primary outcomes

1

Description
tinitus
Timepoint
One month after treatment
Method of measurement
Tinitus handicap inventory questionare

Secondary outcomes

1

Description
Improvement of sleep
Timepoint
One month after treatment
Method of measurement
Pittsburgh sleep questionare

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
Street address
Ayatollah Motahari Blvd, Resalat Square
City
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
Street address
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
Other areas of specialty/work
Street address
Samenolaeme Bulding, Matin 2 Alley, Saeedie Street,Hamedan
City
Hamedan
Postal code
6516713454
Phone
+98 81 3821 7452
Fax
Email
zahraabbasi6485@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Hamedan University Of Medical Sciences
Full name of responsible person
Farhad Farahani
Position
Master,Floaship Of Cochlear Implant And Otology and Neuro_otology
Other areas of specialty/work
Street address
Deputy Of Education, Third floor, Fourth bulding, Front of Hotel Mar Mar, Cross road Abbas Abad, Third Floor,
City
Hamedan
Postal code
65176119664
Phone
+98 81 3252 8052
Fax
+98 81 3252 0203
Email
Farahani@umsha.ac.ir
Web page address

Person responsible for updating data

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
Other areas of specialty/work
Street address
Smaenolaeme Bulding, Matin2 Allay, Saeedie Street, Hamedan
City
Hamedan
Postal code
6516713454
Phone
+98 81 3821 7452
Fax
Email
Zahraabbasi6485@yahoo.com
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