Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effectiveness of the combination of Memantine and Betahistine on insomnia severity, quality of life and severity of symptoms in people with primary tinnitus

Protocol summary

Study aim
The effectiveness of the combination of Memantine and Betahistine on the severity of insomnia, quality of life and severity of symptoms in people with primary tinnitus

Design
Phase 3 randomized clinical trial with parallel groups, with a control group, single-blind, will be conducted on 60 patients. For randomization, 15 blocks will be selected using the random number table (blocks of 4) so that the sample size reaches 60 people.

Settings and conduct
The research setting includes the neurology clinic of Vali Asr Medical Training Center in Zanjan and the research community includes all people with primary tinnitus who refer to the center. Individuals will be selected by the available method and then randomly assigned to the intervention group, Betahistine plus Memantine, and the control group, Betahistine plus placebo. In this study, only patients will be blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: suffering from tinnitus disease for more than 3 months, age 18 to 60 years, having moderate intensity of insomnia. Exclusion criteria: Tinnitus due to anatomical disorder, tumor, previous use of Memantine, history of high blood pressure, suffering from chronic and debilitating diseases, recognized mental illness, concurrent use of drugs that interfere with Memantine, contraindication to use of Memantine

Intervention groups
The intervention group will receive Betahistine tablets (8 mg daily) plus Memantine for up to three months. The schedule for receiving Memantine is as follows: Day 1 to 7: 5 mg; 8th to 14th day: 5 mg twice a day; 15th to 21st day: 5 mg in the morning and 10 mg in the evening; From the 22nd day to the 90th day, 10 mg twice a day The control group will receive Betahistine tablets (8 mg daily) and placebo.

Main outcome variables
Severity of insomnia, quality of life and severity of tinnitus symptoms

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190427043389N4**
Registration date: **2023-08-11, 1402/05/20**
Registration timing: **prospective**

Last update: **2023-08-11, 1402/05/20**
Update count: **0**

Registration date
2023-08-11, 1402/05/20

Registrant information

Name
Hamed Ghavimi

Name of organization / entity

Country
Iran (Islamic Republic of)

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ghavimih@zums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-08-27, 1402/06/05

Expected recruitment end date
2024-05-20, 1403/02/31

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effectiveness of the combination of Memantine and Betahistine on insomnia severity, quality of life and severity of symptoms in people with primary tinnitus

Public title
The effectiveness of the combination of Memantine and Betahistine on insomnia severity, quality of life and severity of symptoms in people with primary tinnitus
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having primary tinnitus for more than 3 months Willingness and interest to participate in the study Having moderate intensity of insomnia (scoring more than 15 based on the ISI Insomnia Severity Questionnaire)
Exclusion criteria:
Tinnitus due to anatomical disease tumor Previous use of memantine History of high blood pressure Suffering from chronic and debilitating diseases as diagnosed by the attending physician Known mental illness Concomitant use of medications that interact with memantine contraindication of memantine by the doctors diagnosis
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Eligible people will be selected from the usual referrals to the neurology clinic of Vali Asr Zanjan educational center by the available method and then will be allocated to two groups by random block method (blocks of 4). The first group will receive Betahistine plus Memantine and the second group will receive Betahistine plus placebo. For this purpose, blocks of 4 will be selected using a table of random numbers in the size of 15 blocks so that the sample size reaches 60 people. Blocking will be done by a person not involved in sampling. Each of the generated random sequences will be recorded on a card and the cards will be placed in the envelopes in order. Finally, the lids of the envelopes will be glued and placed inside a box. At the start of the intervention to identify the order of the participants, one of the envelopes will be opened in order and the assigned group of that participant will be revealed.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, people will be assigned to two groups by random block method (blocks of 4). Patients will be blinded in this study. One group will receive Betahistine tablets along with Memantine tablets, while the other group will receive Betahistine tablets along with a placebo. Placebo tablets are very similar to Memantine tablets in terms of color, shape and size, but do not contain the active drug. Both pills are manufactured by the same pharmaceutical company.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Rsearch Ethics Committee of Zanjan University of Medical Sciences
Street address
Jomhouri Street, Azadi Boulevard, University Headquarters, 1st floor, Deputy of Research and Technology, Zanjan University of Medical Sciences
City
Zanjan
Province
Zanjan
Postal code
4515613191
Approval date
2023-07-18, 1402/04/27
Ethics committee reference number
IR.ZUMS.REC.1402.103

Health conditions studied

1

Description of health condition studied
Severity of tinnitus symptoms
ICD-10 code
H93.1
ICD-10 code description
Tinnitus

2

Description of health condition studied
Insomnia severity
ICD-10 code
G47.0
ICD-10 code description

Insomnia

3

Description of health condition studied
Quality of Life
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Severity of tinnitus intensity
Timepoint
Before intervention and 3 months after the start of the intervention
Method of measurement
Tinnitus severity index standard questionnaire

Secondary outcomes

1

Description
Insomnia severity
Timepoint
Before the start of the intervention and 3 months after the start of the intervention
Method of measurement
ISI Insomnia Severity Index Questionnaire

2

Description
Quality of Life
Timepoint
Before the start of the intervention and 3 months after the start of the intervention
Method of measurement
Standard Quality of Life Questionnaire (SF-36)

Intervention groups

1

Description
Intervention group: 8 mg of Betahistine tablets plus Memantine tablets with instructions to take from the first to the seventh day: 5 mg; 8th to 14th day: 5 mg twice a day; 15th to 21st day: 5 mg in the morning and 10 mg in the evening; From the 22nd day to the 90th day, 10 mg twice a day.
Category
Treatment - Drugs

2

Description
8 mg Betahistine tablets and placebo
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Vali Asr neurology clinic
Full name of responsible person
Hamed Ghavimi
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Vali Asr Medical Education Center, above Valiasr Square
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zanjan 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
Zanjan University of Medical Sciences
Full name of responsible person
Dr. Hamed Ghavimi
Position
academic member
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Medical Pharmacy
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Part of the data, such as the information related to the main outcome, can be shared.
When the data will become available and for how long
three months
To whom data/document is available
researchers
Under which criteria data/document could be used
A person can access the data after requesting the person in charge of the trial and checking her reliability.
From where data/document is obtainable
Central Library of Zanjan University of Medical Sciences
What processes are involved for a request to access data/document
A person can access the data after requesting the person

in charge of the trial and checking her reliability.

Comments