Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Clinical trial of the effect of magnesium compared to placebo in idiopathic tinnitus

Protocol summary

Study aim
The effect of magnesium in idiopathic tinnitus

Design
A phase 2 clinical trial on 60 patients,with a control group, parallel groups, double-blind, randomized design. For simple randomization random.org website will be used.

Settings and conduct
In this study, tinnitus patients who refer to RafidehHospital, Asma Comprehensive Center & Hearing Clinics & meet the inclusion criteria are included. The therapist & the patients will be blinded to the type of medicine received.

Participants/Inclusion and exclusion criteria
Inclusion criteria:Idiopathic tinnitus, Patients over 18 years old and under 65 years old, Informed consent. Exclusion criteria:Taking anticoagulant drugs, Pregnancy or intention to become pregnant, Not feeling well, Observation of any unpredictable complications, Non-cooperation in psychoacoustic assessments, The presence of pulsating tinnitus, History of otological and neurological and Breastfeeding

Intervention groups
In this study, patients with idiopathic tinnitus with some degree of hearing loss will be randomly divided into 2 groups; Intervention group (30 people) will receive a 250 mg magnesium oxide & control group (30 people) will receive 1 placebo orally every day with the same frequency of dose & the duration of treatment will be 2 months.

Main outcome variables
Tinnitus annoyingness index; psychoacoustic level (determining the intensity of tinnitus and its annoyingness); the hearing level of the ear

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160813029327N26**
Registration date: **2024-10-04, 1403/07/13**
Registration timing: **prospective**

Last update: **2024-10-04, 1403/07/13**
Update count: **0**

Registration date
2024-10-04, 1403/07/13

Registrant information

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Ramin Abrishami

Name of organization / entity
Islamic Azad University, Pharamceutical sciences branch

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-11-05, 1403/08/15

Expected recruitment end date
2025-07-06, 1404/04/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Clinical trial of the effect of magnesium compared to placebo in idiopathic tinnitus

Public title
The effect of magnesium in idiopathic tinnitus
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Idiopathic tinnitus Patients over 18 years old and under 65 years old Informed consent
Exclusion criteria:
Taking anticoagulant drugs Pregnancy or intention to become pregnant Not feeling well Observation of any unpredictable complications Non-cooperation in psychoacoustic assessments The presence of pulsating tinnitus History of otological and neurological disease Breastfeeding Vitamin D deficiency
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Random number table: two groups of 30 patients were created using a simple randomization method through the website www.random.org and based on the Random Sequence Generator. To hide the random allocation, the method of opaque sealed envelopes with a random sequence was used. Patients were divided into one of two groups receiving magnesium or receiving placebo based on the sequence of referrals.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study is a double-blind, placebo-controlled study; So that in this study, both the research subject and the therapist are unaware of the patient's medication. Medicines are delivered to the patient in uniform packages marked with a unique code by a third person, and the information about the type of medicine cannot be seen by the therapist.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Pharmaceutical Sciences Unit, Islamic Azad university
Street address
No. 99, Yakhchal Ave., Gholhak, Shariati St., Tehran
City
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Province
Tehran
Postal code
19356466
Approval date
2024-05-25, 1403/03/05
Ethics committee reference number
IR.IAU.PS.REC.1403.081

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 annoyance index and psychoacoustic assessments of tinnitus
Timepoint
At the beginning of the study (before the intervention) and 60 days after starting the treatment
Method of measurement
Tinnitus Handicap Inventory (THI) questionnaire and determination of perceived loudness of tinnitus by the patient through LMT, PMT, MML

Secondary outcomes

1

Description
Hearing threshold
Timepoint
At the beginning of the study (before the intervention) and 60 days after starting the treatment
Method of measurement
Audiogram chart or ear tape

Intervention groups

1

Description
Intervention group:For people who met the criteria for entering the research, they will receive a magnesium tablet in the form of 250 mg tablet - jalinous every day for two months

Category
Treatment - Drugs

2

Description
Control group:In people who met the criteria for entering the research, they will receive a placebo in the form of oral tablets made in Islamic Azad University , every day for two months.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Rafideh specialized hospital

Full name of responsible person
Seyedeh Kiana Moghaddaspour Behrouz

Street address
Shahid Nemati Alley, South Salimi Street, Andarzgoo Blvd., Qeytariyeh

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2

Recruitment center

Name of recruitment center
Asma comprehsive center and heenaring clinics

Full name of responsible person
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Next to 20th Street, Seyed Jamaluddin Asadabadi Street, Yousef Abad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

Full name of responsible person
Masoud Parsania

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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
Islamic Azad University

Proportion provided by this source
100

Public or private sector
Private

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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Younes Lotfi

Position
Specialist doctor and Academic staff

Latest degree
Specialist

Other areas of specialty/work
Ear, Nose, and Throat
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Person responsible for scientific inquiries

Contact
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Person responsible for updating data

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Full name of responsible person
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Student
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A Level or less
Other areas of specialty/work
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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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Patients' Demographic Data,Scores obtained from tinnitus performance questionnaire and hearing threshold
When the data will become available and for how long
After publication of paper, for one year
To whom data/document is available
Academic persons
Under which criteria data/document could be used
Users should refer to the article
From where data/document is obtainable
By sending an email to the corresponding author
What processes are involved for a request to access data/document
By sending an email to the corresponding author
Comments