Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Clinical trial of the effect of selenium in idiopathic tinnitus

Protocol summary

Study aim
Determining the Effect of Selenium Supplementation on Improving the Symptoms of Idiopathic Tinnitus & Introducing the Necessary Supplement to Improve the Symptoms of the Disease

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

Settings and conduct
In this study, tinnitus patients who refer to RafidehHospital, Asma Comprehensive Center & Hearing Clinics & meet the inclusion criteria are selected.The patients will be randomly divided into 2Gp (generally sample size: 60).The intervention group will take 1Se pill daily & the control Gp will take 1placebo pill daily for 2months. Also, the therapist & the patient will be blinded to the type of medicine received. After 2months of the treatment period, the tinnitus annoyance index will be done by the THI questionnaire, psychoacoustic evaluation regarding the severity of tinnitus & its annoyance, as well as an audiogram examination to determine the hearing level of the patient.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Tinnitus with unknown cause, Having normal hearing or mild to severe hearing loss & having a specific age range Exclusion criteria: Use of ACTS, pregnancy, observing any unforeseen complications, simultaneous receipt of drug treatment, history of otological & neurological diseases, breastfeeding

Intervention groups
In this study, patients with idiopathic tinnitus will be randomly divided into 2 gps: Gp1(30 people) will receive a 200 mcg Se supplement daily in the form of a pill & gp2 (30 people) will receive 1placebo orally every day with the same frequency of dose & the duration of treatment will be 2 months.

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

General information

Reason for update
In order to standardize the patient diagnosis process and give more accurate results

Acronym

IRCT registration information
IRCT registration number: **IRCT20160813029327N24**
Registration date: **2024-09-20, 1403/06/30**
Registration timing: **prospective**

Last update: **2024-12-13, 1403/09/23**
Update count: **1**

Registration date
2024-09-20, 1403/06/30

Registrant information

Name
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
2024-09-22, 1403/07/01

Expected recruitment end date
2025-05-22, 1404/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Clinical trial of the effect of selenium in idiopathic tinnitus

Public title
The effect of Selenium on Idiopathic Tinnitus
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having tinnitus that does not have specific pathological examinations. Having normal hearing or Suffering from degrees of mild to severe hearing loss in the frequency range of 250-8000 Hz
Exclusion criteria:
Taking anticoagulant drugs Pregnancy or intention to become pregnant Not being in a good general mood Observing any unforeseen complications Lack of cooperation in psychoacoustic assessments of tinnitus Receiving concomitant medical treatment or other tinnitus rehabilitation History of Otological and Neurological Diseases Breastfeeding Presence of pulsating tinnitus
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Random number table: 2 groups of 30 patients were created by 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 selenium 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 Islamic Azad university of pharmaceutical sciences
Street address
No. 99, Yakhchal Ave., Gholhak, Shariati St., Tehran
City
Tehran
Province
Tehran
Postal code
19356466
Approval date
2024-06-18, 1403/03/29
Ethics committee reference number
IR.IAU.PS.REC.1403.132

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
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

Secondary outcomes

1

Description
Psychoacoustic assessments of tinnitus
Timepoint
At the beginning of the study (before the intervention)

and 60 days after starting the treatment

Method of measurement

Determination of perceived loudness of tinnitus by the patient through LMT(Loudness Matching of Tinnitus), PMT(Pitch Matching of Tinnitus), MML(Minimal Masking Level)

2

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 Selenium supplement in the form of 200 microgram tablet every day for two months - Selenium Health Burst - Porateb Company.

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 every day for two months.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Rafideh specialized hospital

Full name of responsible person

Kimia sadat Rasouli

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

Kimia sadat Rasouli

Street address

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

Street address

Yakhchal St, Shariati st.

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Email

K.rasouli12@gmail.com

Grant name

Grant code / Reference number

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

Yes

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

Name of organization / entity

Islamic Azad University

Full name of responsible person

Ramin Abrishami

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Kimia sadat Rasouli

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

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

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

One year after printing the results and publishing the article

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