Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effect of using selenium in the treatment of tinnitus

Protocol summary

Study aim
Determining the effectiveness of using selenium in the treatment of tinnitus
Design
This study is a clinical trial study in which patients are placed in one of the two groups treated with selenium or the control group without treatment. The sample size is 60 people for each group. Parallel groups, without blinding and phase 3 on 120 patients and randomization with random numbers table
Settings and conduct
This study will be conducted in 1402 in Al-Zahra Hospital in Isfahan on the population of tinnitus patients as a clinical trial. Patients will be randomly divided into control and case groups, and case group patients will be treated with selenium and control group patients will be treated without treatment. The researcher and the participants in this study were randomized with the help of a random number table and sealed envelopes. This study was not blinded.
Participants/Inclusion and exclusion criteria
This study is conducted on people who come with complaints of tinnitus. inclusion criteria includes patients with tinitus and without other underlying diseases
Intervention groups
In this study, patients are divided into two groups, which include the treatment group with selenium and the control group without drugs. Patients in the case group will be treated with selenium capsules 200 mg daily for 30 days, and patients in the control group will not receive any medication.
Main outcome variables
tinnitus severity

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20230417057946N1**
Registration date: **2023-04-24, 1402/02/04**
Registration timing: **prospective**

Last update: **2023-04-24, 1402/02/04**
Update count: **0**
Registration date
2023-04-24, 1402/02/04

Registrant information
Name
Niloofar Masoomnia
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 11 3225 0868
Email address
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-05-22, 1402/03/01
Expected recruitment end date
2023-07-23, 1402/05/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of using selenium in the treatment of tinnitus

Public title
selenium in tinnitus
Purpose
Treatment
Inclusion/Exclusion criteria

Inclusion criteria:
18 to 65 years old informed consent Complaint of tinnitus
Exclusion criteria:
Having psychiatric and/or cognitive disorders that prevent the understanding of tests and questionnaires. Using tinnitus-causing drugs Having any kind of hearing loss Patients with a history of diabetes and hypertension

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

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Based on the sample size of the research, a number of letter envelopes with aluminum wrappers (in order to make the content of the envelopes unclear), preparation and each of the random sequences created with the help of a random number table are recorded on a card and the cards inside the letter envelopes are They are placed in order. In order to maintain a random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the lid of the letter envelopes is glued and placed in a box. At the time of starting the registration of the participants, based on the order of entry into the study, one of the envelopes will be opened and the allocated group of that participant will be revealed in such a way that if the created number is odd, the patient will be in the first group and If the number is even, the patient is placed in the second group.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences

Street address
Hezar Jarib

City
Isfahan

Province
Isfehan

Postal code
8174673461

Approval date
2023-03-30, 1402/01/10

Ethics committee reference number
IR.MUI.MED.REC.1402.045

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 severity

Timepoint
before the study beginning and one month after one month treatment

Method of measurement
tinnitus handicap inventory questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: treatment with selenium. In this group, patients are treated with 200 mg of selenium daily for up to 30 days. Selenium is prescribed in the form of a supplemental tablet made in Iran, under the license of Arnet Pharmaceutical Corp of the United States, after meals once a day for up to 30 days.

Category
Treatment - Drugs

2

Description
Control group: no treatment

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Alzahra hospital

Full name of responsible person
Niloofar Masomnia

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Shaghayegh Haghjoo

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Grant name

Grant code / Reference number

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

Title of funding source
Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Niloofar Masomnia

Position
resident

Latest degree
Medical doctor

Other areas of specialty/work
Ear, Nose, and Throat

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Person responsible for updating data

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Position
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Latest degree
Medical doctor
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
no more information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available