

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 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)

Phone

+98 11 3225 0868

Email address

amnm_80@yahoo.com

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

Isfahan

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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Email

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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 scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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Person responsible for updating data

Contact

Name of organization / entity

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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