Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the effect of hormone replacement therapy on tinnitus in menopausal women.

Protocol summary

Study aim
Determining the effect of hormone replacement therapy on tinnitus in menopausal women

Design
The study is a randomized clinical trial with a control group, with parallel groups, phase 3 on 40 patients. The Rand function of Excel software will be used for randomization.

Settings and conduct
The study will be conducted on postmenopausal women with tinnitus who are referred to the ENT clinic of Besat Hospital, Hamadan. The study is double-blind. The person assessing the outcome and the patient will be unaware of the type of medication used.

Participants/Inclusion and exclusion criteria
Participants were postmenopausal women with moderate to severe tinnitus. Inclusion criteria were menopausal age, tinnitus persisting for at least 3 months, menopause within the past 10 years, and patient consent to participate in the study. Exclusion criteria were depression, calcium, vitamin, and magnesium intake two months before and after the intervention, tinnitus due to drug-induced side effects, patients with conductive or mixed hearing loss, and suspicion and diagnosis of tumoral lesions.

Intervention groups
The intervention group will receive 0.625 mg of conjugated estrogen and 2.5 mg of medroxyprogesterone daily for three months. The control group will receive one placebo tablet (containing starch) that will be packaged in a similar shape and appearance to estrogen for three months.

Main outcome variables
The main outcomes of the study include change in tinnitus severity, tinnitus-related disability, and changes in tinnitus loudness and frequency, which will be assessed before the start of treatment and 3 months after the start of treatment.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20151123025202N46**
Registration date: **2025-07-29, 1404/05/07**
Registration timing: **prospective**

Last update: **2025-07-29, 1404/05/07**
Update count: **0**

Registration date
2025-07-29, 1404/05/07

Registrant information

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-08-23, 1404/06/01

Expected recruitment end date
2026-03-20, 1404/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of hormone replacement therapy on tinnitus in menopausal women.

Public title
The effect of hormone therapy on tinnitus in menopausal women

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Female gender Menopause within the last 10 years Having the patient's consent to participate in the study

Exclusion criteria:
Having depression History of calcium, vitamin, and magnesium intake two months before intervention Tinnitus caused by medication side effects Suspicion and diagnosis of tumoral lesions Patients with conductive or mixed hearing loss

Age
From **50 years** old

Gender
Female

Phase
2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
For the purpose of randomization, 40 cards are prepared, 20 of which are labeled with the letter A and 20 with the letter B, and each card is placed in an aluminum envelope and placed inside a box. When the patients arrive, one of the envelopes will be randomly selected and opened. Based on the letter selected inside, the patient will be assigned to group A or B.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, the placebo will be prepared in a similar shape and color to the original drug. The drug and placebo will be identified by a code. The patient and the person evaluating the treatment outcome will be unaware of the type of treatment.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Hamadan Univercity of Medical Science

Street address
Śahahid Fahmideh

City
Hamadan

Province
Hamadan

Postal code
6517838697

Approval date
2025-07-08, 1404/04/17

Ethics committee reference number
IR.UMSHA.REC.1404.239

Health conditions studied

1

Description of health condition studied
Tinnitus

ICD-10 code
H93.1

ICD-10 code description
Tinnitus

Primary outcomes

1

Description
Change in the intensity of tinnitus

Timepoint
Before treatment and at the end of the third month of treatment

Method of measurement
With visual analog scale

2

Description
Changes in disability scores due to tinnitus

Timepoint
Before treatment and at the end of the third month of treatment

Method of measurement
With the Tinnitus Tinnitus Handicap Inventory (THI)

3

Description
Loudness and frequency of tinnitus

Timepoint
Before treatment and at the end of the third month of treatment

Method of measurement
Audiometric test

Secondary outcomes

1

Description
Occurrence of drug side effects
Timepoint
During treatment
Method of measurement
Questioning the patient

Intervention groups

1

Description
Intervention group: They will receive 0.625 mg of conjugated estrogens and 2.5 mg of medroxyprogesterone daily for three months.
Category
Treatment - Drugs

2

Description
Control group: They will receive one placebo pill (containing starch) daily, which will be packaged in a form and appearance similar to estrogen, for 3 months.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Besat Hospital
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Sponsors / Funding sources

1

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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
Hamedan 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

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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
Undecided - It is not yet known if there will be 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
No - There is not a plan to make this available
Title and more details about the data/document
All data can be shared except for authors names
When the data will become available and for how long
From 2026 onwards it is permissible
To whom data/document is available
Clinical professionals and Researchers in all fields
Under which criteria data/document could be used
For treatment of patients and develop research and science
From where data/document is obtainable
Correspond to the email address of the scientific responsible for the study
What processes are involved for a request to access data/document
Send and receive email
Comments