

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Name

Abbas Moradi

Name of organization / entity

Hamedan University of Medical Of Science

Country

Iran (Islamic Republic of)

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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 University of Medical Science

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Şahahid Fahmideh

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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 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

Full name of responsible person

Farhad Farahani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

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Web page address

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

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Abbas Moradi

Position

Coach

Latest degree

Master

Other areas of specialty/work

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Professor

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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