

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

Effectiveness of topical estrogen on non allergic rhinitis in post menopausal women

Protocol summary

2022-05-16, 1401/02/26

Study aim

Evaluation of the effectiveness of topical estrogen on non allergic rhinitis in postmenopausal women

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 50 patients. Excel software rand function was used for randomization.

Settings and conduct

The drug and placebo were prepared in the same package and given to patients in both groups. The chief physician, researcher and statistical specialist is not aware of the patient group.

Participants/Inclusion and exclusion criteria

Menopausal women 12 months after their last menstrual bleeding; symptoms of nasal congestion (feeling of fullness in the nose, feeling of discomfort and heaviness in the nose - feeling of reduced airflow in the nose, loss of smell or mouth breathing).

Intervention groups

Intervention group: take intra nasal conjugated estrogen ointment daily (50 mg containing 300 micrograms of estrogen) for 3 months; control group treated with lanolin 50 mg daily for 3 months.

Main outcome variables

Improving nasal airflow in rhinomanometry

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200926048841N2**

Registration date: **2022-05-16, 1401/02/26**

Registration timing: **prospective**

Last update: **2022-05-16, 1401/02/26**

Update count: **0**

Registration date

Registrant information

Name

mahboobe asadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2640 5257

Email address

ma_asadi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-22, 1401/03/01

Expected recruitment end date

2023-05-22, 1402/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of topical estrogen on non allergic rhinitis in post menopausal women

Public title

Estrogen in non allergic rhinitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Menopausal women 12 months after their last menstrual bleeding Symptoms of nasal congestion (feeling of fullness in the nose, feeling of discomfort and heaviness in the nose - feeling of reduced airflow in the nose, loss

of smell or mouth breathing)

Exclusion criteria:

Use of drugs affecting the nasal airway and nasal mucosa (systemic and local) Systemic underlying diseases Previous history of rhinoplasty and sinus surgery Obstructive symptoms before menopause Presence of known sinonasal diseases, including pulpitis, chronic sinusitis, sinonasal tumors (both benign and malignant) Smoking and inhaled drugs Occupational exposure to chemical stimulants and its history Patients who did not have the proper cooperation for rhinomanometry, endoscopy and the use of drugs and follow-up Patients for whom estrogen use is contraindicated

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: 25

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization method. Given the block size of 2, there are two ways to assign participants to a block. AB or BA. (A) stands for topical estrogen (B) stands for no topical estrogen. Using Microsoft Excel software we produce 33 numbers equal to the sample size in each group between 0 to 10. For numbers 0, 2, 4, 6, 8, AB combination and for numbers 1, 3, 5, 7, 9, BA combination are chosen.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patients and physician is not aware of the patient's group; also researchers and the study statisticians were masked to treatment allocation.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hearing Disorders Research center of Shahid Beheshti University of Medical Si

Street address

Hearing Disorders Research center, Loghman Hakim hospital, Kamali ave., South Kargar ave.

City

Tehran

Province

Tehran

Postal code

1916665354

Approval date

2021-10-23, 1400/08/01

Ethics committee reference number

IR.SBMU.RETECH.REC.1401.025

Health conditions studied

1

Description of health condition studied

Vasomotor rhinitis

ICD-10 code

J30.0

ICD-10 code description

Vasomotor rhinitis

Primary outcomes

1

Description

Effect of estrogen on rhinitis

Timepoint

Three months after treatment

Method of measurement

Rhinomanometry

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Take intra nasal conjugated estrogen ointment daily(50 mg containing 300 micrograms of estrogen) for 3 months.

Category

Treatment - Drugs

2

Description

Control group: They were treated with intranasal lanolin (oil used as a base for estrogen ointment)daily (50mg)for 3 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani hospital

Full name of responsible person

Mahboobe Asadi

Street address

Velenjak, Erabi Ave

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Province

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Postal code

191666354

Phone

+98 21 2303 1317

Email

mahboobeh_farvardin@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyed Ali Ziai

Street address

Evin, Shahid Shahriary square.

City

Tehran

Province

Tehran

Postal code

193954719

Phone

+98 21 2243 9951

Email

aliziai@sbm.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Research Assistant of Shahid Beheshti University of medical sciences

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

Mahboobe Asadi

Position

Assistant professor

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Person responsible for updating data

Contact

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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

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Participant data sets are to be shared

When the data will become available and for how long

These data files will become available one year after publication

To whom data/document is available

The data is only available for people working in academic institutions

Under which criteria data/document could be used

The data is only available for people working in academic institutions

From where data/document is obtainable

The data is obtainable from the corresponding author via email

What processes are involved for a request to access data/document

The data is obtainable from the corresponding author via email

Comments