Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 Oct 2026

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

Protocol summary

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
2022-05-16, 1401/02/26

Registrant information
Name
mahboobe asadi
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 21 2640 5257
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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 esterogen 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 wlho 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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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.
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193954719
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aliziai@sbmu.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 Beheshty 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
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Person responsible for updating data

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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