Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of effect of vitamin E vaginal cream with vaginal estradiole on atrophic vaginitis among menopausal women.

Protocol summary

Study aim
Comparison of effect of vitamin E vaginal cream with vaginal estradiole on atrophic vaginitis among menopausal women.

Design
In this research, 72 eligible menopausal women who affected by atrophic vaginitis and over active bladder syndrome, referring to Tabriz health centers will be chosen and will be randomly divided into two groups of control and intervention. Group allocation will be concealed by assigning a unique code to each participants.This trial is a study in Phase zero.

Settings and conduct
The intervention group (receiving vitamin E vaginal cream containing 100 IU of vitamin E in half of the applicator) and control group (receiving conjugated estrogen vaginal cream with a dose of 0.625 mg in half of applicator containing 0.3 mg of conjugated estrogen), will use the half of the vaginal cream applicator deeply every night during the first week and two nights every week in the following weeks. The duration of the intervention will be eight weeks. The location of study will be in Tabriz health centers.

Participants/Inclusion and exclusion criteria
Menopausal women older than 45 years which having inclusion and exclusion criteria.

Intervention groups
The intervention group (receiving vitamin E vaginal cream containing 100 IU of vitamin E) and the control group (receiving conjugated estrogen vaginal cream whit a dose of 0.625 mg), half the applicator every night in the first week and in the following weeks 2 nights per week, will use for eight weeks.

Main outcome variables
Score of symptoms of atrophic vaginitis

General information

Reason for update
Correction of sample size

Acronym

IRCT registration information
IRCT registration number: **IRCT20150424021917N12**
Registration date: **2021-06-13, 1400/03/23**
Registration timing: **prospective**

Last update: **2022-07-31, 1401/05/09**
Update count: **1**

Registration date
2021-06-13, 1400/03/23

Registrant information

Name
Sevil Hakimi

Name of organization / entity
Tabriz University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-06-22, 1400/04/01

Expected recruitment end date
2021-11-22, 1400/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of effect of vitamin E vaginal cream with

vaginal estradiole on atrophic vaginitis among menopausal women.

Public title
Comparison of effect of vitamin E vaginal cream with vaginal estradiole on atrophic vaginitis among menopausal women.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Physiologic menopause women Having sexual activity Affected by atrophic vaginitis(having 3 signs out of 5 signs) Affected by over active bladder syndrome (score 3 of the OABSS questionnaire)

Exclusion criteria:
Vaginal bleeding Hormone replacement therapy during last 3 months History of breast cancer or any type of estrogen dependent cancer History of breast cancer in first grade relatives (ex. mother, sister) Estrogen contraindications include a history of gallstones, a history of venous thrombosis, any type of vascular disease, the presence of thrombophlebitis. Taking anticoagulants

Age
From **45 years** old to **56 years** old

Gender
Female

Phase
2

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
Randomized

Randomization description
In this research, randomization will be done using random blocks size 4 and 6. Randomization will be individual randomization. For randome allocation, vitamin E vaginal cream and conjugated estrogen cream are put in opaque envelopes. On the envelopes A and B code and numbers are written. Envelops will be given to the participants respectively.

Blinding (investigator's opinion)
Triple blinded

Blinding description
In this study, participants, researcher and data analyzer will be blind. Each type of drugs will be the same according to smell, shape and color. the drugs will be accepted code A or B. This code is clarified only of drug formulation specialist. So the participants, researcher and data analyzer will be blind. After data analyzing formulation specialist will be clarified that each code of A and B belong to which group.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences

Street address
Faculty of Nursing & Midwifery, South Shariaty Street

City
Tabriz

Province
East Azarbaijan

Postal code
5138947977

Approval date
2021-05-02, 1400/02/12

Ethics committee reference number
IR.TBZMED.REC.1400.098

Health conditions studied

1

Description of health condition studied
Atrophic Vaginitis

ICD-10 code
N95.2

ICD-10 code description
Senile (atrophic) vaginitis

Primary outcomes

1

Description
Score of symptoms of atrophic vaginitis

Timepoint
Vaginal symptoms score will be measured before and 8 weeks after the start of the intervention.

Method of measurement
For evaluation of this variable we will use of standard questionnaire.

Secondary outcomes

1

Description
Score of symptoms of overactive bladder syndrome

Timepoint
Score of symptoms of overactive bladder syndrome will be measured before and 8 weeks after the start of the intervention.

Method of measurement
A standard questionnaire is used to measure this variable.

2

Description
Satisfaction score
Timepoint
Satisfaction score of the drug will be measured 8 weeks after the start of the intervention.
Method of measurement
A standard questionnaire is used to measure this variable.

3

Description
frequency of side effects
Timepoint
frequency of side effects, will be measured 8 weeks after the start of the intervention.
Method of measurement
A standard questionnaire is used to measure this variable.

Intervention groups

1

Description
Intervention group: vitamin E vaginal cream containing 100 IU of vitamin E in half of the applicator. The half of the vaginal cream applicator is used every night during the first week and two nights every week in the following weeks
Category
Treatment - Drugs

2

Description
Control group: conjugated estrogen vaginal cream with a dose of 0.625 mg in half of applicator containing 0.3 mg of conjugated estrogen. The half of the vaginal cream applicator is used every night during the first week and two nights every week in the following weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ahar city health centers
Full name of responsible person
Sevil Hakimi
Street address
Sheikh Shahabuddin Ave, Ahar, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Mohammad Samiei
Street address
Research department, Third floor, Central construction, Number 2, Tabriz medical science university, Golgasht Street, Azadi Avenue, Tabriz
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Samiei.moh@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Sevil Hakimi
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
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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
No - There is not 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
No - There is not a plan to make this available
Title and more details about the data/document
Primary and secondary outcomes, as well as side events will be distributed.
When the data will become available and for how long
Six months after publication of results.
To whom data/document is available
Records will be distributed of academic researchers and " research and development" units of pharmaceutical companies.
Under which criteria data/document could be used
" Research and development" unit of each pharmaceutical companies can use of records. All requests will be evaluated after receiving formal e- mail and telephone or face to face negotiation.
From where data/document is obtainable
Sevil Hakimi hakimis@tbzmed.ac.ir
What processes are involved for a request to access data/document
The applicant notifies the applicant by email, after receiving the email the results are sent.
Comments