# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Jun 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
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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
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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.
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Midwifery
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## Person responsible for scientific inquiries

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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**