# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 2026

## Comparison of fenufreek extract vaginal cream with ultra low dose conjugated estrogen vaginal cream on atrophic vaginitis among menopausal women.

### Protocol summary

**Study aim**
Comparison of fenugreek extract vaginal cream with conjugated estrogen vaginal cream on atrophic vaginitis

**Design**
In this research, 60 eligible menopausal women who affected by atrophic vaginitis, 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.

**Settings and conduct**
Participants in intervention group will revived vaginal cream of fenugreek extract 5% 2 times per week for 12 weeks. Women in the control group will recieved vaginal cream of conjugated estrogen .0625 mg , half of applicator 2 times per week for 12 weeks. The location of study will be in Abbasi health center.

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

**Intervention groups**
They will revived vaginal cream of fenugreek extract 5% 2 times per week for 12 weeks.

**Main outcome variables**
Vaginal symptoms Vaginal maturation index

### General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20150424021917N7**
Registration date: **2018-02-10, 1396/11/21**
Registration timing: **prospective**

Last update: **2018-02-10, 1396/11/21**
Update count: **0**

**Registration date**
2018-02-10, 1396/11/21

**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**
2018-02-20, 1396/12/01

**Expected recruitment end date**
2018-09-23, 1397/07/01

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Comparison of fenufreek extract vaginal cream with ultra low dose conjugated estrogen vaginal cream on atrophic vaginitis among menopausal women.

**Public title**
Comparison of fenufreek extract vaginal cream with ultra low dose conjugated estrogen vaginal cream on atrophic vaginitis.

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Menopausal women Physiologic menopasue Having sexual avtivity Affected by atrophic vaginitis

**Exclusion criteria:**

Vaginal bleeding Hormone replacement therapy during last 3 months History of breast cancer or ant type of estrogen dependent cancer History of breast cancer in first grade relatives (ex. mother, sister) Estrogen contraindication including history of vein thrombosis, any type of vascular disease, thrombophlebitis,

**Age**

From **45 years** old to **55 years** old

**Gender**

Female

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **60**

More than 1 sample in each individual

Number of samples in each individual: **2**

Sample in each participant is Pap smear.

**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. The tool of randomization is random allocation software (RAS). For randome allocation, frenugreek extract 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**

Daneshgah Street, Tabriz University of Medical Science

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614766

**Approval date**

2018-01-01, 1396/10/11

**Ethics committee reference number**

IR.TBZMED.REC.932

## 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**

vaginal symptoms score

**Timepoint**

Vaginal symptoms score will be measured before and 12 weeks after start id intervention.

**Method of measurement**

For evaluation of this variable we will use of standard questionnare

### 2

**Description**

Vaginal maturation index is the second main outcome.

**Timepoint**

Vaginal maturation index will be measured before and 12 weeks after start id intervention.

**Method of measurement**

This index is indicated to proportion of parabasal, intermediate and superficial cellules . We will taken pap smear from participants. Percent of superficial cellules will be multiply in 1, percent of intermediate cellules will be multiply in 0.5 and percent of parabasal cellules will be multiply in 0. After that all of numbers will be summed.

## Secondary outcomes

### 1

**Description**
Vaginal pH
**Timepoint**
Before and 12 weeks after intervention
**Method of measurement**
Vaginal pH will be measured with using of pH meter kits.

### 2

**Description**
Satisfaction from treatment
**Timepoint**
12 weeks after start of intervention
**Method of measurement**
With using of questionnare

## Intervention groups

### 1

**Description**
Intervention group: ،They will received vaginal cream of fenugreek extract 5%, 0.5 gram or half of applicator twice per week for 12 weeks.
**Category**
Treatment - Drugs

### 2

**Description**
Control group: They will received vaginal cream of conjugated estrogen 0.625mg, 0.5 gram or half of applicator twice per week for 12 weeks.
**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Abbasi Health Center
**Full name of responsible person**
Sevil Hakimi
**Street address**
Abbasi Street
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## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Tabriz University of Medical Sciences
**Full name of responsible person**
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**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**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**
Assistant Professor
**Latest degree**
Ph.D.
**Other areas of specialty/work**
Gynecology and Obstetrics
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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**

Response person is: Dr. Sevil Hakimi Address: Iran, Tabriz, Shariati street, school of nursing and midwifery

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

After 6 months of results publication a request via email is enough for taking records. ! week after receiving request, records are ready for distribution.

**Comments**

There is no extra explanation.