Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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
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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
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Abbasi Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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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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.