

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The comparison the effect of flaxseed and Conjugated Estrogen vaginal cream in vaginal atrophy and sexual satisfaction of postmenopausal women.

Protocol summary

Study aim

Objective: To compare the effect of conjugated Estrogens and flaxseed vaginal cream in the treatment vaginal atrophy and sexual satisfaction in postmenopausal women

Design

Purchase of Flaxseed, extraction, ointment and sampling within 7 months, vaginal application by the patient, vaginal atrophy test and statistical analysis

Settings and conduct

The present study is a randomized, triple blind (research unit, researcher, statistic analyst), clinical trial of two groups. Selection of research units in an accessible and randomized manner in two groups of intervention and control in 60 postmenopausal women. the examination of women in gynecologic clinic of Ghaem Hospital is carried out by the researcher. In the intervention group, the vaginal cream of flaxseed and in the control group. The intervention is 8 weeks, which is received in the first two weeks of each night and then twice a week until the end of the study period. Assessment of atrophy and sexual satisfaction Overall, prior to the study, 4 and 8 weeks after the start of the study wick evaluated by atrophy criteria and Larsson questionnaire are considered. Follow-up on drug use is conducted on a weekly basis at 2 and 6 weeks.

Participants/Inclusion and exclusion criteria

Having amenorrhea for at least 12 months or 6 months with normal FSH more than 40, normal pap smears over the past 3 years and verifying the atrophy PH and degree of maturation of the patient's vaginal cells. Exit criteria include abnormal vaginal bleeding, allergy to Estrogen and Flaxseed .

Intervention groups

In the intervention group, Flaxseed vaginal cream and in the control group the conjugated Estrogen vaginal

Main outcome variables

Treatment method (Vaginal cream conjugated estrogen, flax seed vaginal cream). Atrophy treatment success rate at 4 and 8 weeks after starting treatment Sexual satisfaction 4 and 8 weeks after starting treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181027041473N1**

Registration date: **2019-01-09, 1397/10/19**

Registration timing: **registered_while_recruiting**

Last update: **2019-01-09, 1397/10/19**

Update count: **0**

Registration date

2019-01-09, 1397/10/19

Registrant information

Name

fahimeh shakeri

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-22, 1397/09/01

Expected recruitment end date

2019-06-22, 1398/04/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The comparison the effect of flaxseed and Conjugated Estrogen vaginal cream in vaginal atrophy and sexual satisfaction of postmenopausal women.

Public title
The comparison the effect of flaxseed and Conjugated Estrogen vaginal cream in vaginal atrophy and sexual satisfaction of postmenopausal women.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Having a willingness to participated in the study Married and have sexual activity age range of 40-65 years Have literacy to read and write Amenorrhoea has been followed for at least 12 months or 6 months amenorrhoea with FSH> 40. Have normal Pap smear in the past 3 years Clinic diagnosis of vaginal atrophy through a set of criteria including: score 65 or more (based on the VAS visual criteria) of the scale of the most vaginal annoyance symptoms (MBS) and having at least 2 signs of the descriptive evaluation table of vaginal mucus, PH> 5 and VMV≤55 (vaginal maturation grade).
Exclusion criteria:
Abnormal bleeding vaginal (pink to brown spotting or clear bleeding). have chronic illness such as diabetes, arthritis, cardiovascular disease, active liver disease or gallbladder disease. having vaginal infection allergy to estrogen or flax seed compounds don't suffering of endometrial cancer or breast cancer Endometrial cancer or breast cancer known or suspected . Consumer Products hormonal vaginal or transdermal than 4 weeks prior to the study and use of oral estrogen, uterine progesterone 8 weeks before the study and use of implants progesterone and estrogen injections for 3 months and pellets of estrogen and progesterone injections 6 months prior to the study to be

Age
From **40 years** old to **65 years** old

Gender
Female

Phase
3

Groups that have been masked

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

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description

Randomization by using spss software is done.

Blinding (investigator's opinion)
Triple blinded

Blinding description
In comparison, the control and intervention groups of their vaginal cream flaxseed and estrogen were apparently identical, therefore, the sample case and evaluators, analysts and sample allocators are blind to the groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences
Street address
Quraishi Building, university street, Mashhad.
City
Mashhad
Province
Razavi Khorasan
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91735951

Approval date
2018-10-21, 1397/07/29

Ethics committee reference number
IR.MUMS.NURE.REC.1397.051

Health conditions studied

1

Description of health condition studied
atrophy and sexual satisfaction

ICD-10 code
N95.2

ICD-10 code description
Postmenopausal atrophic vaginitis

Primary outcomes

1

Description
atrophy and sexual satisfaction treatment

Timepoint
Performing the intervention then measuring vaginal atrophy and sexual satisfaction in the fourth and eighth weeks.

Method of measurement

Using vaginal maturation index of more than 55 and a vaginal pH of more than 5 and gaining a score of 65 or more from the scale of the most vaginal annoying symptoms and having at least two signs of the symptoms of a descriptive evaluation table of vaginal mucus.

Secondary outcomes

empty

Intervention groups

1

Description

Control group: use conjugated estrogen vaginal cream for 8 weeks, so that the first two weeks every night, then twice a week until the end of the study period

Category

Treatment - Drugs

2

Description

Intervention group: Use flaxseed vaginal cream for 8 weeks so that the first two weeks every night once, then twice a week until the end of the study period

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital Women's Clinic

Full name of responsible person

Dr. Nafiseh Saghafi

Street address

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2

Recruitment center

Name of recruitment center

Um Al-Banin Hospital Women's Clinic

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad 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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Fahimeh shakeri

Position

MSc Student Midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available