Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 wich 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

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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

Postal code

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
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2

Recruitment center
Name of recruitment center
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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
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
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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