

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Comparison of the effectiveness of Flaxseed oil vaginal gel with lubricant vaginal gel on the vaginal dryness in postmenopausal women

Protocol summary

Study aim

Determining the effect of Flaxseed oil vaginal gel compared to vaginal lubricant gel on vaginal dryness in postmenopausal women

Design

In this research, 94 eligible patients with vaginal dryness referring to Persian Medicine Clinic Ahmadiyeh were chosen purposefully and a code was allocated to each one of them. Then, patients were randomly divided into two control and intervention groups

Settings and conduct

After the explanation of the study for people referring to Persian Medicine Clinic Ahmadiyeh who have Inclusion criteria, all participants are given consent. The pelvic exam was performed and the Vaginal Health Index (VHI) is determined and Iam is provided to determine Vaginal Maturation Index (VMI). Subjective symptoms of vaginal dryness include dyspareunia, vaginal burning, dryness and vaginal itching based on visual analog scale will be recorded. Patients are randomly assigned to one of the groups and take the drug vaginally with the applicator 3 nights a week for 8 consecutive weeks. They will be visited at weeks 0, 2, 4, and 8, and all tests will be repeated at the end of the study

Participants/Inclusion and exclusion criteria

Inclusion criteria: Postmenopausal women aged 45-65 years, Menopause diagnosis with one of these symptoms: had a history of at least 1 year of amenorrhea or a high level of follicle-stimulating hormone (FSH) above 40 or bilateral oophorectomy: Non-Inclusion criteria: history of oral estrogen consumption in the 8 weeks prior to study, active vaginal infection, systemic disease

Intervention groups

Flaxseed oil vaginal gel: Vaginal lubricant gel

Main outcome variables

Subjective symptoms of vaginal dryness include burning, dyspareunia, itching and dryness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160402027170N2**

Registration date: **2017-12-20, 1396/09/29**

Registration timing: **prospective**

Last update: **2017-12-20, 1396/09/29**

Update count: **0**

Registration date

2017-12-20, 1396/09/29

Registrant information

Name

Fatemeh Nejatbakhsh

Name of organization / entity

medical University Tehran

Country

Iran (Islamic Republic of)

Phone

+98 21 6675 4151

Email address

nejatbakhsh@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-21, 1396/11/01

Expected recruitment end date

2019-01-21, 1397/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of Flaxseed oil vaginal gel with lubricant vaginal gel on the vaginal dryness in postmenopausal women

Public title

The efficacy of Flaxseed oil on the vaginal dryness

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Postmenopausal women aged 65-45 Menopause diagnosis with one of these symptoms: had a history of at least 1 year of amenorrhea or a high level of follicle-stimulating hormone (FSH) above 40 or bilateral oophorectomy

Exclusion criteria:

History of oral estrogen consumption in the 8 weeks prior to study Active vaginal infection Systemic disease

Age

From **45 years** old to **65 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **94**

Randomization (investigator's opinion)

Randomized

Randomization description

Allocation to treatment groups was conducted by an independent researcher using a random number sequence, generated with a computer-generated randomization scheme, according to a randomized block design. The block size was six. The randomization list was concealed from the primary researcher who enrolled and assessed participants in sequentially numbered, sealed, opaque envelopes

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Central building of Tehran University of Medical Sciences, near Quds St., Keshavarz Ave

City

Tehran

Province

Tehran

Postal code

1417733161

Approval date

2016-02-22, 1394/12/03

Ethics committee reference number

IR.TUMS.REC.1394.2057

Health conditions studied

1

Description of health condition studied

Vaginal dryness in postmenopausal women

ICD-10 code

N95.2

ICD-10 code description

Postmenopausal atrophic vaginitis

Primary outcomes

1

Description

Score of vaginal dryness in Visual Analogue Scale (VAS)

Timepoint

Before the intervention begins, the end of the intervention

Method of measurement

Visual Analogue Scale (VAS)

2

Description

Score of vaginal burning in Visual Analogue Scale (VAS)

Timepoint

Before the intervention begins, the end of the intervention

Method of measurement

Visual Analogue Scale (VAS)

3

Description

Score of vaginal itching in Visual Analogue Scale (VAS)

Timepoint

Before the intervention begins, the end of the intervention

Method of measurement

Visual Analogue Scale (VAS)

4

Description

Score of dyspareunia in Visual Analogue Scale (VAS)

Timepoint

Before the intervention begins, the end of the

intervention
Method of measurement
Visual Analogue Scale (VAS)

Secondary outcomes

1

Description

Score of Vaginal Health Index (VHI)

Timepoint

Before the intervention begins, the end of the intervention

Method of measurement

Vaginal Health Index (VHI) questionnaire

2

Description

Percentage of Vaginal Maturation Index (VMI)

Timepoint

Before the intervention begins, the end of the intervention

Method of measurement

Vaginal Maturation Index (VMI) questionnaire

Intervention groups

1

Description

Intervention group: Flaxseed oil vaginal gel with the applicator 3 nights a week for 8 consecutive weeks

Category

Treatment - Drugs

2

Description

Control group: Lubricant vaginal gel with the applicator 3 nights a week for 8 consecutive weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Persian Medicine Clinic Ahmadiieh

Full name of responsible person

Nejatbakhsh Fatemeh

Street address

No 27, Corner Alley Tabriz, Sarparast Shomali Str,
Taleghani Ave

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1416663361

Phone

+98 21 8899 0837

Email

Nejatbakhsh@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Sahraeian, Vice Chancellor for research of Tehran
University of Medical Sciences

Street address

Central building of Tehran University of Medical
Sciences, near Quds St., Keshavarz Ave.

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Rojarahimi@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Nejatbakhsh Fatemeh

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Nejatbakhsh Fatemeh
Position
Associate professor
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Ph.D.
Other areas of specialty/work
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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Title and more details about the data/document

Information about the main outcome after unidentifiable people can be shared

When the data will become available and for how long

Since print results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

The data can be used by Iranian and non-Iranian researchers in the field of medical sciences in order to perform IPD Meta-analysis and mentioning the name of the corresponding author of the original article in the colleagues of the secondary article. Other analyzes (other statistical models) are not acceptable and researchers are not allowed to use data to write initial studies.

From where data/document is obtainable

Email the corresponding author of the article
Nejatbakhsh@tums.ac.ir

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

The requester sends a letter to the corresponding author of the article and sends a valid certificate of employment in academic and scientific institutions. The author responds within a maximum of 3 weeks and sends the data file

Comments