

# 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 lam 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

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

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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+98 21 8899 0837

##### **Email**

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

##### **Street address**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
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**Other areas of specialty/work**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Nejatbakhsh Fatemeh  
**Position**  
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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