

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### Evaluation the Effect of Fenugreek Vaginal Cream on Vaginal Atrophy in Postmenopausal Women

#### Protocol summary

##### Summary

The aim of this study was to evaluate the effects of Fenugreek vaginal cream on treatment vaginal atrophy in postmenopausal women. This study is randomized, double-blind. study is carry out at East Ahwaz number one health center. Inclusion criteria: Age between 45 to 65, Amenorrhea at less 12 month or have hormone test with FSH level more than 40 unit, Presenting symptom of vaginal atrophy, Have Sexual activity and single partner. Exclusion criteria: Vaginal infection, Genital Abnormalities, The use of Sex Hormones within the 8 weeks preceding study,smoke and alcohol user. Genital Bleeding of unknown Cause, Use of Phytoestrogens such as Soy, Red clover, Fenugreek, Vitex within the last one Month, They are divided into two groups receiving Fenugreek vaginal cream 5% (n=30 ) and placebo (n=30) for 8 weeks. The symptoms of vaginal atrophy evaluation by a self-assessed 4-point scale of composite score was determined ( none, mild, moderate and severe). Vaginal pH and maturation value measured before and after interventions and compared in both groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017010331705N2**

Registration date: **2017-02-09, 1395/11/21**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-02-09, 1395/11/21

##### Registrant information

###### Name

Fakhriyeh Mazalzadeh

##### Name of organization / entity

Ahwaz Jundishapur University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3443 9419

##### Email address

mazal.f@ajums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research, Ahwaz JundiShapur University of Medical Sciences

##### Expected recruitment start date

2017-01-20, 1395/11/01

##### Expected recruitment end date

2017-05-22, 1396/03/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation the Effect of Fenugreek Vaginal Cream on Vaginal Atrophy in Postmenopausal Women

##### Public title

Evaluation the Effect of Fenugreek Vaginal Cream on Vaginal Atrophy in Postmenopausal Women

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

inclusion criteria: Age between 45 to 65; Amenorrhea at less 12 month or have hormone test with FSH level more than 40 unit; Presenting symptom of vaginal atrophy; Have Sexual activity and single partner; Exclusion criteria; Vaginal infection; Genital Abnormalities; The use

of Sex Hormones within the 8 weeks preceding study; user of smoke and alcohol and etc; Genital Bleeding or spotting of unknown Cause; Use of Phytoestrogens such as Soy; Red clove; Fenugreek; Vitex within the last one Month.

**Age**

No age limit

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: 60

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethical Committee of Ahwaz Jundishapur University of Medical Science

**Street address**

Department of Research and Information Technology  
University of Medical Sciences, Ahwaz Jundishapur,  
Ground Floor, City University, Ahwaz

**City**

Ahwaz

**Postal code****Approval date**

2016-12-03, 1395/09/13

**Ethics committee reference number**

IR.Ajums.REC.1395.556

**Health conditions studied****1****Description of health condition studied**

Atrophy Vaginal in post menopausal women

**ICD-10 code**

N95.2

**ICD-10 code description**

Postmenopausal Atrophic Vaginitis

**Primary outcomes****1****Description**

percentage of Maturity vaginal

**Timepoint**

Before and after eight weeks (end of intervention)

**Method of measurement**

Vaginal smear

**2****Description**

Vaginal Atrophy

**Timepoint**

Before intervention, Two weeks after the intervention,  
Four weeks after intervention, Eight weeks after  
intervention

**Method of measurement**

Kupperman Index Questionnaire

**3****Description**

Vaginal PH

**Timepoint**

Before and after eight weeks (end of intervention)

**Method of measurement**

By PH meter strips

**Secondary outcomes****1****Description**

Sexual function

**Timepoint**

Before and after intervention

**Method of measurement**

Female Sexual Function Index (FSFI) questionnaire

**2****Description**

Temperament

**Timepoint**

Before and after intervention

**Method of measurement**

Temperament questionnaires

**3****Description**

Dyspareunia

**Timepoint**

Before intervention, Two weeks after the intervention,  
Four weeks after intervention, Eight weeks after  
intervention

**Method of measurement**

self-assessed 4-point scale of composite score

#### 4

**Description**

menopausal symptoms

**Timepoint**

Before intervention, 2, 4, 8 weeks after intervention

**Method of measurement**

Kupperman Index Questionnaire

#### 5

**Description**

severity of menopausal symptoms

**Timepoint**

Before intervention, 2, 4, 8 weeks after intervention

**Method of measurement**

Menopause Rating Scale (MRS) questionnaire

#### 6

**Description**

Sexual satisfaction

**Timepoint**

Before and after intervention

**Method of measurement**

Larson's sexual satisfaction questioner

### Intervention groups

#### 1

**Description**

Cream Vaginal Fenugreek 5% one Applicator daily for 8 week

**Category**

Treatment - Drugs

#### 2

**Description**

control group (placebo) one applicator daily for 8week

**Category**

Placebo

### Recruitment centers

#### 1

**Recruitment center****Name of recruitment center**

East's number one health center in Ahwaz

**Full name of responsible person**

Fakhriyeh Mazalzadeh

**Street address**

67 Abasi, St. Zetoon Karmandi, Ahwaz Iran

**City**

Ahwaz

### Sponsors / Funding sources

#### 1

**Sponsor****Name of organization / entity**

Vice chancellor for research, Ahwaz JundiShapur University of Medical Sciences

**Full name of responsible person**

SHaref Makhmalzadeh

**Street address**

Ahwaz Jundishapur University of Medical Sciences, opposite the central building, Vice Chancellor for Research, Ahwaz University of Medical Sciences,

**City**

Ahwuz

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice chancellor for research, Ahwaz JundiShapur University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

### Person responsible for general inquiries

**Contact****Name of organization / entity**

Ahwaz Jundishapur University of Medical Sciences

**Full name of responsible person**

Fakhriyeh Mazalzadeh

**Position**

Student Master of Midwifery

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**Web page address**

**Sharing plan**

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

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*