

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

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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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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