

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Comparison of the Effectiveness of Vaginal Cream contain extract of *Foeniculum vulgare*; *Salvia officinalis*. L; Flaxseed; on Vaginal atrophy in postmenopausal Women referred to selected health care centers undercover of Ahvaz Jundishapour medical university in 1398

Protocol summary

Study aim

Determination of the Effectiveness of Vaginal Cream contain extract of *Foeniculum vulgare*; *Salvia officinalis*. L; Flaxseed; on the Treatment of Vaginal atrophy in postmenopausal Women

Design

In this study, 80 postmenopausal women with vaginal atrophy and inclusion criteria were randomly divided into intervention and control groups.

Settings and conduct

Sample size is 80 and the duration of the intervention is 8 weeks. First, patients are examined for vaginal atrophy and the checklist for symptoms of vaginal atrophy is completed by the researcher. Vaginal discharge is taken to examine vaginal mucosal maturation index, and vaginal pH by a pH meter. Individuals are randomly assigned to one of two groups. An intervention group (Vaginal Cream content extract of *Foeniculum vulgare*; *Salvia officinalis*. L; Flaxseed) and a control group (placebo vaginal gel) receive an application for 8 weeks. At the end of weeks 2, 4 and 8, patients are evaluated again in terms of clinical signs of vaginal atrophy and vaginal atrophy syndrome. At the end of the study, vaginal pH and vaginal discharge samples are re-examined.

Participants/Inclusion and 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 within the last one month.

Intervention groups

The intervention group (Vaginal Cream content extract of *Foeniculum vulgare*; *Salvia officinalis*. L; Flaxseed) and control group (placebo vaginal cream)

Main outcome variables

Treatment of vaginal atrophy; Reducing the complications of vaginal atrophy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190616043909N1**

Registration date: **2020-04-05, 1399/01/17**

Registration timing: **retrospective**

Last update: **2020-04-05, 1399/01/17**

Update count: **0**

Registration date

2020-04-05, 1399/01/17

Registrant information

Name

Golshan tahmasebi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 4362 8502

Email address

golshanthm@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-23, 1398/06/01
Expected recruitment end date
2020-02-20, 1398/12/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the Effectiveness of Vaginal Cream contain extract of Foeniculum vulgare; Salvia officinalis. L; Flaxseed; on Vaginal atrophy in postmenopausal Women referred to selected health care centers under cover of Ahvaz Jundishapour medical university in 1398

Public title
Comparison of the Effectiveness of Vaginal Cream contain extract of Foeniculum vulgare; Salvia officinalis. L; Flaxseed; 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:
Genital abnormalities; breast diseases with unknown reason; liver cholestatic disorders; renal failure; vaginal infection needing treatment; genital bleeding or spotting with unknown reason; hormone therapy or using sex hormones within the 2 months before the study; using of phytoestrogens such as soy, red clover, fenugreek, and vitex within the last one month; body mass index more than 30 .

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

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization method and description: randomization unit: Individual Concealment method: opaque and closed envelopes Create random sequence: generate random numbers by Excel software.

Blinding (investigator's opinion)
Triple blinded

Blinding description
In this study; the participant; researcher and evaluator of

the outcome are kept blind by coding the drug and placebo.

Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Valiasr Street, intersection of Niayesh

City

Tehran

Province

Tehran

Postal code

1983969411

Approval date

2019-02-25, 1397/12/06

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1397.261

Health conditions studied

1

Description of health condition studied

Vaginal Atrophy in Postmenopausal Women

ICD-10 code

N95.2

ICD-10 code description

Postmenopausal atrophic vaginitis

Primary outcomes

1

Description

Symptom of vaginal atrophy

Timepoint

At the beginning of the study, 4 weeks and 8 weeks after intervention

Method of measurement

The most bothersome symptom checklist

2

Description

Clinical signs of vaginal atrophy

Timepoint

At the beginning of the study, 2 weeks, 4 weeks and 8

weeks after intervention
Method of measurement
Check list of clinical signs of vaginal atrophy

3

Description
Vaginal maturation index
Timepoint
Before intervention and after intervention
Method of measurement
Vaginal Smear

4

Description
Vaginal acidity
Timepoint
Before intervention and after intervention
Method of measurement
PH meter

Secondary outcomes

1

Description
Sexual function
Timepoint
Before and after intervention
Method of measurement
Female Sexual Function Index (FSFI) questionnaire

Intervention groups

1

Description
Intervention group:Foeniculum Vulgare, Salvia Officinalis and Flax Seed extracts vaginal cream, every night, an applicator for 8 weeks
Category
Treatment - Drugs

2

Description
Control group: Vaginal gel Placebo, every night, an applicator for 8 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Health Center No. 1
Full name of responsible person
Golshan Tahmasebi
Street address

Shaheed Gandami Street, opposite side of Hoda intermedieat School, between Rastegari and Vakili

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Golshan Tahmasebi
Street address
Shahid Chamran Highway, Yemeni Avenue, next to Taleghani Hospital
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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Golshan Tahmasebi
Position

Masters of Midwifery student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for updating data

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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