

# 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

**City**  
Ahwaz  
**Province**  
Khuzestan  
**Postal code**  
6173663369  
**Phone**  
+98 61 3377 4366  
**Email**  
golshan.tahmasebi70@gmail.com

## 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  
**City**  
Ahwaz  
**Province**  
Khuzestan  
**Postal code**  
1985717443  
**Phone**  
+98 21 23871  
**Email**  
info@sbmu.ac.ir  
**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

**Street address**

Golestan, Farvardin Street, Vahid Alley, Noran Complex 5

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Ahwaz

**Province**

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**Postal code**

6391715991

**Phone**

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Sharareh Jannessari

**Position**

teacher

**Latest degree**

Master

**Other areas of specialty/work**

Midwifery

**Street address**

Vali Asr Ave., Intersection of Niayesh, Shahid Beheshti Faculty of Nursing and Midwifery

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Tehran

**Province**

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**Postal code**

11858118581

**Phone**

+98 21 8820 2512

**Email**

shararehjannessari@gmail.com

**Person responsible for updating data**

**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

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**Postal code**

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**Phone**

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**Email**

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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