

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Aug 2026

### The comparison of the efficacy *Foeniculum vulgare* and placebo on atrophy vaginal and sexual function in postmenopausal women

#### Protocol summary

##### Summary

The goal of this study is to assess the effects of *Foeniculum vulgare* on vaginal atrophy and sexual function. Inclusion criteria were: postmenopausal status, which was defined as aged between 45-65 with no vaginal bleeding for 1 year; no regular ingestion of phytoestrogen or soy-based products; having a normal mammogram in the last year; vaginal infection; smoking; Currently (or in the past 6 months) using estrogen ; no regular physical exercise or allergy to *Foeniculum vulgare*. In a double-blind, randomized, placebo-controlled trial, 60 postmenopausal women recruiting in Imam Reza Hospital in Mashhad were randomized to fennel (n=30) and placebo group (n=30) using random table. Maturation Index and marital satisfaction were measured at baseline and after three months. Also, placebos and fennel capsules were identical in terms of shape and size

Iran (Islamic Republic of)

##### Phone

+98 34 4230 9487

##### Email address

ghazanfarpm901@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Mashhad

##### Expected recruitment start date

2014-05-12, 1393/02/22

##### Expected recruitment end date

2016-05-22, 1395/03/02

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016091628789N2**

Registration date: **2016-11-11, 1395/08/21**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-11-11, 1395/08/21

##### Registrant information

##### Name

Masumeh Ghazanfarpour

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Country

##### Scientific title

The comparison of the efficacy *Foeniculum vulgare* and placebo on atrophy vaginal and sexual function in postmenopausal women

##### Public title

the effect of fennel on vaginal dryness

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria were: postmenopausal status, which was defined as aged between 45-65 with no vaginal bleeding for 1 year; no regular ingestion of phytoestrogen or soy-based products; having a normal mammogram in the last year; vaginal infection; smoking; Currently (or in the past 6 months) using estrogen ; no regular physical exercise; allergy to *Foeniculum vulgare*

##### Age

From **44 years** old to **64 years** old

##### Gender

Female

**Phase**  
3

**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

Ethics Committee of Biomedical research, Mashhad  
University of Medical Sciences

##### Street address

Ghoreishi building, Daneshgah street, Khorasan  
Razavi , Mashhad, Islamic Republic Of Iran

##### City

Mashhad

##### Postal code

#### Approval date

2010-09-23, 1389/07/01

#### Ethics committee reference number

IR.mums.ac.ir.1392.151

## Health conditions studied

### 1

#### Description of health condition studied

Vaginal atrophy

#### ICD-10 code

N95.2

#### ICD-10 code description

Postmenopausal atrophic vaginitis

## Primary outcomes

### 1

#### Description

Atrophy Vaginal

#### Timepoint

before and three months after intervention

## Method of measurement

Maturation index

### 2

#### Description

Marital satisfaction

#### Timepoint

before and three months after intervention

#### Method of measurement

Marital Satisfaction Scale

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Foeniculum vulgare 30 mg soft capsule, three times a  
day,12 week

#### Category

Treatment - Drugs

### 2

#### Description

placebo capsule 30 mg soft capsule, three times a  
day,12 week

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Gynecology Clinic of Emam Reza

##### Full name of responsible person

Maliheh Afiat

##### Street address

Gynecology Clinic, Emam Reza Hospital, Ebn-e Sina  
Street, Mashhad, Khorasan-e-Razavi,

##### City

Mashhad

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mashhad University of Medical Sciences, Vice  
chancellor for research

##### Full name of responsible person

Mohsen Tafaghodi

##### Street address

Ghoreishi building, Daneshgah street, Khorasan  
Razavi , Mashhad, Islamic Republic Of Iran

**City**  
Mashhad

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**  
Yes

**Title of funding source**  
Mashhad University of Medical Sciences, Vice chancellor for research

**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**  
Mashhad University of Medical Sciences

**Full name of responsible person**  
Mohsen Tafaghodi

**Position**  
Vice chancellor for research

**Other areas of specialty/work**

**Street address**  
Ghoreishi building, Daneshgah street, Khorasan Razavi , Mashhad, Islamic

**City**  
Mashhad

**Postal code**

**Phone**  
+98 51 3843 7840

**Fax**

**Email**  
tafaghodim@mums.ac.ir

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Mashhad University of Medical Sciences

**Full name of responsible person**  
Masumeh Ghazanfarpour

**Position**  
PhD candidate of Reproductive Health

## Other areas of specialty/work

### Street address

Department of Midwifery, School of Nursing and Midwifery, Mashhad University of Medical Sciences, Ebn-e Sina St, Mashhad, Iran

### City

Mashhad

### Postal code

### Phone

+98 513152455

### Fax

### Email

Masumeh.ghazanfarpour@yahoo.com

### Web page address

## Person responsible for updating data

### Contact

#### Name of organization / entity

Mashhad University of Medical Science

#### Full name of responsible person

Masumeh Ghazanfarpour

#### Position

Reproductive Health

#### Other areas of specialty/work

#### Street address

Department of Midwifery, School of Nursing and Midwifery, Mashhad University of Medical Sciences, Ebn-e Sina St., Mashhad, Iran

#### City

Mashhad

#### Postal code

#### Phone

00

#### Fax

#### Email

Masumeh.ghazanfarpour@yahoo.com

#### 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*