

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 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

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

Iran (Islamic Republic of)

Phone

+98 34 4230 9487

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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

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

Vagnal 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 Reaza 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

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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
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

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Person responsible for scientific inquiries

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Position
PhD candidate of Reproductive Health

Other areas of specialty/work

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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