Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of Foeniculum vulgare and St John’s wort (Hypericum perforatum) on the climacteric symptoms and sexual activity in menopausal woman attending in selected gynecology clinics of shiraz university of medical sciences,1391.

Protocol summary

Summary

The present clinical, randomized, single-blind, placebo-controlled trial aimed to determine the effect of Foeniculum vulgare and St John’s wort on the climacteric symptoms and sexual dysfunction in menopausal women. The study population included the menopausal women from 45 to 60 years old attending the selected gynecology clinics of Shiraz University of Medical Sciences which had agreed to cooperate with the researchers. The study subjects were also required to have the following criteria: at least 12 months being passed from their last menstrual, FSH more than40. In case the study subjects suffered from any illness, were not willing to continue participating in the study, and showed allergic reactions to medication, they were excluded from the study. After all, a total of 105 subjects were entered into the study and randomly divided in to three groups of 35 receiving the drug and the placebo, respectively for 8 weeks.climacteric complaints were evaluated using Green climacteric scale and Female Sexual Function Index at two follow up visits.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201207281548N15**
Registration date: **2012-08-25, 1391/06/04**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-08-25, 1391/06/04

Registrant information

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Recruitment status

Recruitment complete

Funding source

Deputy of Research of Shiraz University of Medical Sciences

Expected recruitment start date

2012-08-22, 1391/06/01

Expected recruitment end date

2012-12-21, 1391/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Foeniculum vulgare and St John’s wort (Hypericum perforatum) on the climacteric symptoms and sexual activity in menopausal woman attending in selected gynecology clinics of shiraz university of medical sciences,1391.

Public title

Evaluation of the effect of two herbal medicine on the

climacteric symptoms and sexual activity in menopausal women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: having general health according to the Goldberg's questionnaire; i.e., getting under23 score, being married and between 40 and 60 years old, not using vitamin supplements, not using soya, not having used hormone therapy during the last 3 months, not using anti-depression,and tranquilizer drugs, amenorrhea for at least 6 months, and FSH more than 40. Exclusion criteria: Suffering from liver, kidney, and digestive diseases, inability to continue taking medication for any reason, unwillingness to cooperate after the beginning of the study, and showing allergic reactions to medication.

Age

From **45 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **105**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Medical Research Ethics Committee of Shiraz University of Medical Sciences

Street address

zand sq

City

shiraz

Postal code

Approval date

2012-07-10, 1391/04/20

Ethics committee reference number

ct-91-6109

Health conditions studied

1

Description of health condition studied

menopause

ICD-10 code

N95.1

ICD-10 code description

Symptoms such as flushing, sleeplessness, headache, lack of concentration, associated with menopause

Primary outcomes

1

Description

Improvement of clinical symptoms

Timepoint

4 weeks

Method of measurement

Green Questionnaire

Secondary outcomes

1

Description

Improve sexual function

Timepoint

4 weeks

Method of measurement

Female Sexual Function Index

Intervention groups

1

Description

Oral placebo tablets three times daily for 8 weeks

Category

Placebo

2

Description

Fennel, soft capsule, 30 mg orally, three times daily for 8 weeks

Category

Treatment - Drugs

3

Description

Hypericum perforatum,160 mg oral tablet, three times daily for 8 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
outpatient academic medical center of Zeynabiyeh Hospital
Full name of responsible person
Street address
City
shiraz

2

Recruitment center
Name of recruitment center
outpatient academic medical center of Hafez Hospital
Full name of responsible person
Street address
City
shiraz

3

Recruitment center
Name of recruitment center
outpatient academic medical center of Shahid Faghihi Hospital
Full name of responsible person
Street address
City
shiraz

4

Recruitment center
Name of recruitment center
Motahhari Clinic
Full name of responsible person
Street address
City
shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr Gholam Reza Hattam
Street address
Deputy for Research, seventh Floor, the central structure of Shiraz University of Medical Sciences, next to the Red Crescent, Zand Avenue
City
shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
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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