Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jun 2026

Effect of Of fennel capsule and evening primrose oil on the symptoms of menopause and sex hormones in postmenopausal women who referred to clinics of Shiraz University of Medical Sciences

Protocol summary

Study aim
Effect of fennel capsule and evening primrose oil on the symptoms of menopause and sex hormones in postmenopausal women

Design
Clinical trial with control group, simple sampling and sample size150, blind, randomized

Settings and conduct
The study population is all postmenopausal women aged 45-60 years referred to the clinics of Shiraz University of Medical Sciences and sampling will be done in an easy method based on purpose based on inclusion criteria and then divided into two intervention groups and a control group with a table of random numbers. it is going to happen. For people who have the criteria to enter the research and want to participate in the research, the questionnaire of demographic characteristics, the criterion of menopause will be completed and the research samples will be divided into two groups based on a random number table and a control group of 50 people. In this way, the intervention groups will take placebo capsules containing fennel and evening primrose oil and the control group will take placebo capsules. The contents of capsules A, B and C will be preserved for unknown samples and clinical caregivers, so the present study will be double-blind.

Participants/Inclusion and exclusion criteria
Entry requirements: 1-Failure to receive HRT 2- Not getting breast cancer treatment (hormone therapy) 3- Lack of surgery in ovarian tumors Non-arrival conditions: 1- Sudden increase or decrease of weight in the sample 2- Any reason that increases or decreases the level of estrogen in the body 3- For any reason, a person has to have hormone therapy 4- Any sign indicating that allergy to fennel and evening primrose oil has manifested itself 5- Examples that can cause menstrual disorder for any reason

Intervention groups
The intervention groups uses fennel capsules and evening primrose oil and a control group of placebo capsules

Main outcome variables
Menopause symptoms

General information

Reason for update
At the time of the project, the conditions for using another herbal medicine, namely evening primrose oil, were available, so a trial was conducted in three groups.

Acronym

IRCT registration information
IRCT registration number: **IRCT20160404027207N2**
Registration date: **2018-04-24, 1397/02/04**
Registration timing: **prospective**

Last update: **2022-05-30, 1401/03/09**
Update count: **1**

Registration date
2018-04-24, 1397/02/04

Registrant information

Name
Fatemeh Ghavi
Name of organization / entity
Jahrom University of Medical Sciences
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-05-02, 1399/02/13
Expected recruitment end date
2020-11-18, 1399/08/28
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of Of fennel capsule and evening primrose oil on the symptoms of menopause and sex hormones in postmenopausal women who referred to clinics of Shiraz University of Medical Sciences

Public title
Effect of Of fennel capsule and evening primrose oil on the symptoms of menopause and sex hormones in postmenopausal women
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Lack of surgery in ovarian tumors Not getting breast cancer treatment (hormone therapy) Failure to receive HRT Women aged 45 to 60 years
Exclusion criteria:
Sudden increase or decrease of weight in the sample Any reason that increases or decreases the level of estrogen in the body For any reason, a person has to have hormone therapy Any sign indicating that allergy to fennel and evening primrose oil has manifested itself Examples that can cause menstrual disorder for any reason
Age
From **45 years** old to **60 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **150**
Randomization (investigator's opinion)
Randomized
Randomization description
Sampling was performed by easy method based on purpose based on inclusion criteria and then divided into two groups of intervention and a control group using a table of random numbers.
Blinding (investigator's opinion)
Double blinded
Blinding description
The intervention groups use capsules containing fennel and evening primrose oil and the control group used placebo capsules. All capsules will be in similar packages with codes A, B and C. The contents of capsules A, B, and C will be preserved for unknown samples and clinical caregivers. Therefore, the present study will be two blinds.
Placebo
Used
Assignment
Other
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shiraz university of medical sciences
Street address
Faculty of Nursing and MidwiferyShiraz., Namazi Sqaure
City
shiraz
Province
Fars
Postal code
71944
Approval date
2017-12-09, 1396/09/18
Ethics committee reference number
IR. SUMS. REC. 1396. 136

Health conditions studied

1

Description of health condition studied
Menopausal and female climacteric states
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Menopause symptoms
Timepoint
Before intervention, two months after the intervention
Method of measurement
Hormones, SF36 General Measurement of Quality of Life, MRS A tool for assessing the severity of postmenopausal women's symptoms

Secondary outcomes

1

Description
Hormonal changes
Timepoint
Before intervention, two months after the intervention
Method of measurement
Elisa Methode

2

Description
Evaluation of the quality of life of postmenopausal women
Timepoint
Before intervention, two months after the intervention
Method of measurement
A general tool for assessing the quality of life SF36

3

Description
Evaluation of severity of symptoms of postmenopausal women
Timepoint
Before intervention, two months after the intervention
Method of measurement
A special tool for assessing the severity of symptoms of postmenopausal women MRS

Intervention groups

1

Description
Intervention groups one: The first group of 30 mg capsules of fennel extract for two months and orally twice a day.
Category
Prevention

2

Description
Intervention group two: 1000 mg capsules of evening primrose oil for two months and orally twice a day.
Category
Prevention

3

Description
Control group: Oral capsules of 100 mg placebo for 2 months twice a day.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shiraz University of Medical Sciences clinics
Full name of responsible person
Ghavi Fatemeh
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Faculty of Nursing and Midwifery., Namazi Square
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr Janghorban Roxana
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Shiraz University of Medical Sciences, Setad Blvd., Shiraz
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researchnu@sums.ac.ir
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
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
Shiraz University of Medical Sciences

Full name of responsible person
Ghavi Fatemeh

Position
Instructor of Faculty Member of Nursing and Midwifery School

Latest degree
Master

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
Not applicable

Informed Consent Form
No - There is not 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
Not applicable

Data Dictionary
Not applicable