Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

A comparative study on the effect of “Black Cohosh” and “Evening Primrose Oil” on women suffering from menopausal hot flashes who refer to Gynecology clinic of Fatemeieh hospital

Protocol summary

Summary

The present study aimed to compare and evaluate the effects of 2 different herbal drugs (black cohosh and evening primrose oil) to improve menopausal hot flashes and quality of life during postmenopause. Main inclusion criteria are women who have not experienced menstruation in last 12 months and having normal blood pressure and the main exclusion criteria are Severe cardiovascular, metabolic, thromboembolic, endocrine, thyroid, or malignant diseases. In this randomized, double blind trial 80 postmenopausal women with hot flashes who refer to Gynecology clinic of Fatemieh Hospital will be randomly assigned into two interventional groups A and B. Drugs are placed in the similar exclusive packets, encoding with A and B. Packets are given to the gynecologist and she will open the packets and read the code of each group. Then group A will be given 40 mg of black cohosh twice a day and group B will receive 500 mg evening primrose oil twice a day for 8 continues weeks. The severity and number of hot flashes and effect of them on quality of life is measured and statistically analyzed by four-point scale , and the Menopause-Specific Quality of Life Questionnaire, receptively at the beginning and end of weeks 1,4 and 8 after initiation of treatment and then superior treatment is suggested.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016041827452N1**
Registration date: **2016-05-12, 1395/02/23**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-05-12, 1395/02/23

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Hamedan University of Medical Sciences

Expected recruitment start date

2016-04-09, 1395/01/21

Expected recruitment end date

2016-10-22, 1395/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study on the effect of “Black Cohosh” and “Evening Primrose Oil” on women suffering from menopausal hot flashes who refer to Gynecology clinic of Fatemeieh hospital

Public title

Comparison of effects of Black cohosh and Evening Primrose oil on Menopausal Hot Flashes

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Women who have not experienced menstruation in last 12 months; Having normal blood pressure(with or without drugs); No use of anti depressants and anxiolytics during last month; No use of estrogens and progesterones in last 6 months; No use of anticoagulants; Not suffering from asthma and allergy. Exclusion criteria: Patients with severe cardiovascular; Metabolic; Thromboembolic; Endocrine; Thyroid or malignant diseases; Uncontrolled Hypertension; Using hormone or medications interfering with vasomotor symptoms in 4 weeks prior to the study; Improper use of herbal drugs;Allergy to drugs; Changing of living place
Age
From **49 years** old to **62 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Hamedan University of Medical Sciences
Street address
Hamedan University of Medical Sciences, Ayatollah kashani blv, Khaje rashid cross
City
Hamedan
Postal code
Approval date
2016-04-09, 1395/01/21
Ethics committee reference number
IR.UMSHA.REC.1395.17

Health conditions studied

1

Description of health condition studied
hot flashes and vasomotor symptoms related to menopause
ICD-10 code
N95.1
ICD-10 code description
Menopausal and female climacteric states

Primary outcomes

1

Description
number and intensity of hot flashes
Timepoint
baseline, end of 1st,4th and 8th week
Method of measurement
four-point scale

Secondary outcomes

1

Description
quality of life
Timepoint
baseline, end of weeks 1,4 and 8
Method of measurement
MENQOL (the Menopause-Specific Quality of Life Questionnaire)

Intervention groups

1

Description
40 mg of black cohosh extract for 8 weeks
Category
Treatment - Drugs

2

Description
500 mg of evening primrose oil twice a day for 8 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Gynecology Clinic of Fatemieh Hospital
Full name of responsible person
Dr. Azami Fard
Street address
City
Hamedan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Amir Mohammad Fallahian
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Ilia apartment, Laleh alley, Shahid nazemi, pasdaran street
City
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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
Hamedan 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
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Person responsible for updating data

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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