

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 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 Fatemeieh 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

Name

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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

Hamedan

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

Name of organization / entity

Hamedan University of Medical Science

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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