

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effect of evening primrose oil on some of the consequences in postmenopausal women

Protocol summary

Summary

The aim of this study was to determine the effect of menopause Evening primrose oil menopausal symptoms. This study was a clinical trial, single center, triple blinded, with random allocation. The population of the study was the eligible postmenopausal women referred to health centers in the Dastena. Inclusion criteria were diagnosis of menopause, not using any hormonal drugs, having normal Pap test during the previous year, complaining about menopausal symptoms, willing to participate in the research, lack of underlying diseases, having a minimum literacy education. The women with inappropriate use of drugs, appearance of severe digestive disorders, symptoms of sensitivity to drug, and not involvement in the completion of questionnaire were excluded. With a randomly allocation, 100 menopause women were allocated in two Evening primrose oil pearl and the placebo groups (50 in each group). Pearls including's menopause Evening primrose oil and placebo had similar shape and had placed in the same box that was encoded numbers 1 to 100. The participants selected one drug box at the time of referral and used twice in day for 30 days. The menopausal symptoms were evaluated in three phases at the beginning of the study, after 15 days and one month after intervention. day for a month. . Kuperman questionnaire to assess symptoms of menopause. MRS, depression, anxiety, sexual dysfunction, sleep quality, etc. will be used.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017012432161N1**

Registration date: **2017-06-19, 1396/03/29**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-06-19, 1396/03/29

Registrant information

Name

Bahare Motaghi Dastenaei

Name of organization / entity

Shahrekord University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 38 3333 3217

Email address

b.motaghi@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahrekord University of Medical Sciences

Expected recruitment start date

2015-03-20, 1393/12/29

Expected recruitment end date

2017-02-19, 1395/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of evening primrose oil on some of the consequences in postmenopausal women

Public title

The effect of evening primrose oil on menopausal symptoms

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: diagnosis of menopause, not using any hormonal drugs, having normal Pap test during the previous year, complaining about menopausal symptoms, willing to participate in the research, lack of underlying diseases, having a minimum literacy education. Exclusion criteria: improper use of medications; severe digestive disorders; signs of sensitivity to medications; lack of participation in the survey

Age

From **48 years** old to **65 years** old

Gender

Female

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahrekord University of Medical Sciences

Street address

Shahrekord University of Medical Sciences. Kashani
Bld. Shahrekord

City

Shahrekord

Postal code

8838136115767

Approval date

2011-04-21, 1390/02/01

Ethics committee reference number

89/11-6

Health conditions studied

1

Description of health condition studied

menopause

ICD-10 code

N95.1

ICD-10 code description

Menopausal and female climacteric states. Symptoms such as flushing, sleeplessness, headache, lack of concentration, associated with menopause

Primary outcomes

1

Description

Physical consequences

Timepoint

at the beginning of the study, after 15 days and one month after intervention.

Method of measurement

researchers Made questionnaire, interview, examination

2

Description

Sexual consequences

Timepoint

at the beginning of the study, after 15 days and one month after intervention.

Method of measurement

Female Sexual Function Index- FSFI

3

Description

mental consequences

Timepoint

at the beginning of the study, after 15 days and one month after intervention.

Method of measurement

interview

Secondary outcomes

1

Description

Quality of Life

Timepoint

at the beginning of the study, after 15 days and one month after intervention.

Method of measurement

Quality of Life Questionnaire sf36

Intervention groups

1

Description

Intervention: 1 pearl (1gr) of Evening Primrose oil twice a day, with a glass of water for 30 days.

Category

Treatment - Drugs

2

Description

control group: 1 pearl (1gr) of placebo twice a day, with a glass of water for 30 days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dastena health center

Full name of responsible person

Bahare Motaghi Dastenaei

Street address

Dastena Health Center, Razi St.

City

Dastena

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahrekord University of Medical Sciences

Full name of responsible person

Dr.Sayed Kamal Solati

Street address

Shahrekord University of Medical Sciences. Kashani

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Shahrekord

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahrekord 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

Shahrekord University of Medical Sciences

Full name of responsible person

Bahare Motaghi Dastenaei

Position

Master

Other areas of specialty/work

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Person responsible for scientific inquiries

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Dastenaei Motaghi Bahare

Position

Lecturer, faculty member

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Web page address

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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