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

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Name of organization / entity
Shahrekord University of Medical Sciences
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Iran (Islamic Republic of)
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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 Bld. Shahrekord
City
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
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Other areas of specialty/work
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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