Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of oral consumption of evening primrose oil on menopausal symptoms in 45-60 years old menopausal women

Protocol summary

Study aim
To determine the effectiveness of evening primrose oil supplements on menopausal symptoms
Design
Clinical trials with drug and placebo control group, treatment-based, with parallel groups, blind, randomized by block method
Settings and conduct
This is a clinical trial study on women with menopausal symptoms referred to gynecological clinics of Khaleej-e-fars hospital in Bandar Abbas. Participants will be randomly divided into two groups. One group will receive evening primrose oil oral supplementation and the other group will receive placebo. All participants will be blind to type of treatment. Two months later, menopausal symptoms will be evaluated by Menopausal Rating Scale.
Participants/Inclusion and exclusion criteria
Women with menopausal symptoms who will be referred to gynecological clinics of Khaleej-e-fars hospital in Bandar Abbas
Intervention groups
Participants will be randomly divided into 2 groups A and B. To group A, evening primrose oil supplementation will be provided from Nature Life factory manufactured in Canada with a dose of 1000 mg/d for 8 weeks. Group B will be given a placebo.
Main outcome variables
Menopausal symptoms

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20181107041585N2**
Registration date: **2019-03-11, 1397/12/20**
Registration timing: **registered_while_recruiting**
Last update: **2019-03-11, 1397/12/20**
Update count: **0**
Registration date
2019-03-11, 1397/12/20

Registrant information
Name
Fatemeh Darsareh
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 76 3355 4515
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famadarsareh@yahoo.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-02-20, 1397/12/01
Expected recruitment end date
2019-06-22, 1398/04/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of oral consumption of evening primrose oil on menopausal symptoms in 45-60 years old menopausal women

Public title
Effect of oral consumption of evening primrose oil on menopausal symptoms
Purpose
Treatment
Inclusion/Exclusion criteria

Inclusion criteria:
Age between 45 and 60 years old Married 12 months amenorrhea Normal pap smear in past12 months Normal finding in physical examinations
Exclusion criteria:
serious chronic medical conditions

Age
From **45 years** old to **60 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **200**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization method: Simple Random unit: Individual Randomization Tool: Sealed Envelope

Blinding (investigator's opinion)
Double blinded

Blinding description
In order to blind the allocation, the pills will be divided into the opaque A and B packets and numbered. Participant, clinical caregiver, researcher, and outcome evaluator will be unaware of the type of intervention.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Bandar Abbas University of Medical Sciences

Street address
Bagh Monir st. Amir Abad

City
Bandar Abbas

Province
Hormozgan

Postal code
7918796758

Approval date
2019-01-30, 1397/11/10

Ethics committee reference number
IR.HUMS.REC.1397.314

Health conditions studied

1

Description of health condition studied
Menopausal symptoms

ICD-10 code
N95.1

ICD-10 code description
Menopausal and female climacteric states

Primary outcomes

1

Description
Menopausal symptoms score

Timepoint
Before intervention and at the end of second month of intervention

Method of measurement
Menopausal Rating Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: evening primrose oil 1000 milligram every day for 8 weeks

Category
Treatment - Drugs

2

Description
Control group: consumption of placebo every day for 8 weeks

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Khaleej Fars hospital

Full name of responsible person
Fatemeh Darsareh

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bandare-abbas University of Medical Sciences
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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
Bandare-abbas 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
Bandare-abbas University of Medical Sciences
Full name of responsible person
Fatemeh Darsareh
Position
Midwife
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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
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available