Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of vitamin b6 and omega-3 supplementation on hot flashes and mood states in menopause women

Protocol summary

Study aim
This study aimed to determine the effect of omega-3 and vitamin B6 supplements compared to omega-3 alone on menopausal symptoms.

Design
This design is a randomized, double-blind, placebo-controlled clinical trial. Simple randomization method is used for randomization. This study is conducted on at least 60 postmenopausal women with menopausal symptoms who are randomly divided into two intervention groups and one control group.

Settings and conduct
This study will be conducted in the nutritional counseling and diet therapy office in Karaj city. After selecting the samples, none of the sample people know about randomization and the process of allocation to groups. Also, the researcher will not know the contents of the packages. Therefore, the present study is double-blind.

Participants/Inclusion and exclusion criteria
Eligibility criteria: Iranian nationality, literate, age 40-60 years, 12 months or more of menopause, natural menopause, complaints of hot flashes and mood problems at the time of the research; Conditions of non-entry: use of hormonal drugs and sedatives, recent experience of stressful factors such as death of close relatives or separation from spouse, etc., suffering from diseases such as diabetes, blood pressure and mental illnesses, history of spotting and uterine bleeding, treatment Active medicine for menopause symptoms, menopause caused by surgery, history of drug and tobacco use, sports activity more than 150 minutes per week.

Intervention groups
The intervention group was randomly given daily omega-3 fatty acids and vitamin b6 (omega-3 1000 mg + vitamin B6 40 mg; n = 20) or daily omega-3 fatty acids (omega-3 1000 mg; n = 20) or Placebo (n = 20) will be given daily for 8 weeks.

Main outcome variables
Severity of menopause symptoms

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231227060537N1**
Registration date: **2024-02-24, 1402/12/05**
Registration timing: **prospective**

Last update: **2024-02-24, 1402/12/05**
Update count: **0**

Registration date
2024-02-24, 1402/12/05

Registrant information

Name
Roxana Abdolmaleki

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-03-01, 1402/12/11

Expected recruitment end date
2024-04-30, 1403/02/11

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The effect of vitamin b6 and omega-3 supplementation on hot flashes and mood states in menopause women

Public title
The effect of Omega-3 and Vitamin B6 supplements on menopausal symptoms

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Iranian nationality literate age 40 to 60 years 12 months or more have passed since the cessation of menstruation normal menopause At the time of the research, she complained of hot flashes and mood problems

Exclusion criteria:
Taking hormonal drugs and sedatives Active drug therapy for vasomotor symptoms Experiencing stressful factors such as the death of a first-degree relative or separation from a spouse Suffering from diseases such as blood pressure, diabetes, mental diseases History of drug and tobacco use Activity more than 150 minutes per week

Age
From **40 years** old to **60 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization method; In this method, each member of the desired society is selected with the same probability.To randomize the three groups, we generate a random number between 1 and 3 using the computer, according to the number of the studied sample; Then each number is written on a card and placed in an envelope, and the envelopes are sealed, and the patient number is written on each envelope, and the first patient who is registered in the study and enters the study is given the envelope corresponding to patient no. 1, patient number 2 will be given envelope number 2 and so on, and this work will continue until the end of the study sample. In order to maintain randomization, the person who prepares the envelopes (research assistant) will be different from the person who registers the patients and provides the envelopes to the patients (researcher).

Blinding (investigator's opinion)
Double blinded

Blinding description
After selecting the samples, none of the sampled people will know about randomization and the process of allocation to groups. The numbered numbers are given to the researcher by the assistant of the researcher and the patients are entered into the study in the order of the numbers, and the researcher will not know about the contents of the packages. Therefore, the present study is double-blind. Also, the pill package of each group is the same in terms of shape, color and size and is delivered to the client in the package.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Islamic Azad University- Science and Research Branch

Street address
3rd floor, Unit 6, No. 153, Khayyam East St., Mehravila North

City
Karaj

Province
Alborz

Postal code
3133617853

Approval date
2022-11-15, 1401/08/24

Ethics committee reference number
IR.IAU.SRB.REC.1401.275

Health conditions studied

1

Description of health condition studied
Menopausal symptoms, hot flashes, mood states

ICD-10 code
F28

ICD-10 code description
Other psychotic disorder not due to a substance or known physiological condition

Primary outcomes

1

Description
Severity of menopause symptoms

Timepoint
The beginning of the study, the end of the eighth week

Method of measurement
Based on the Menopause Rating Scale (MRS)

questionnaire

2

Description
mood states
Timepoint
The beginning of the study, the end of the eighth week
Method of measurement
based on The Mood and Anxiety Symptoms Questionnaire (MASQ-D30)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: daily intake of omega 3 fatty acids and vitamin b6 capsules (omega 3 1000 mg + vitamin B6 40 mg) for 8 weeks
Category
Treatment - Drugs

2

Description
Intervention group: Daily intake of omega 3 fatty acids capsules (omega 3 1000 mg) for 8 weeks
Category
Treatment - Drugs

3

Description
Control group: Daily intake of placebo capsules (placebo 1000 mg) for eight weeks
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Roxana Abdolmaleki Nutrition and Diet Therapy Center
Full name of responsible person
Roxana Abdolmaleki
Street address
3rd floor, Homa building, Nasim dead end, North Taleghani
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
dr Radfar
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Science and Research Branch,shodada Hesarak blvd, Daneshgah Square,Sattari Highway
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Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Islamic Azad University
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
Islamic Azad University
Full name of responsible person
Roxana Abdolmaleki
Position
Master student
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information.
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
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available