

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 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

+98 26 3442 1653

Email address

roxanaabdolmaleki@gmail.com

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

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Email

roxanaabdolmaleki@gmail.com

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

City

Karaj

Province

Alborz

Postal code

3153653619

Phone

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

dr Radfar

Street address

Science and Research Branch, shodada Hesarak blvd, Daneshgah Square, Sattari Highway

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1477893855

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+98 21 4486 5154

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dabir@srb.iau.ir

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

Bachelor

Other areas of specialty/work

Nutrition

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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