

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The Comparison of the Effect of Omega3 and Folic Acid Oral Tablet on Hot Flashes in Menopausal Women

Protocol summary

Summary

Objective: The Comparison of the Effect of Omega3 and Folic Acid Oral Tablet on Hot Flashes in Menopausal Women(2) **Study design:** The sampling will be random and triple blind. This study will be placebo-controlled and single center. The study population : Iranian origin of all menopausal women with hot flashes,Sample size: 120 (3): In this semi-experimental study will participate 120 menopausal women with hot flashes (4): **Inclusion criteria :** Iranian, age 45-60 years, menopause is the normal type have,reporting at least two times hot flashes per day , with literacy being studied components or a family member, body mass index 20 to 30, non receiving hormone therapy , anti-depressants or tranquilizers, supplements and herbal medicines, no known underlying disease (hypertension, diabetes, epilepsy, etc.), the lack of experience of such as relatives died in the last 6 months of stress, separation of spouses and absence of estrogen-dependent cancer, non consumption of more than 2 servings of fish per weeks, insensitivity to fish or fish oil, seafood, avoiding the use of any drugs to improve the symptoms of hot flashes, at least one year and a maximum of three years have menstruation, exercise not more than 2 times a week for 20-30Dqyqh,Exclusion criteria: the other drug use during the study, in case of complications or allergic drugs (omega-3 or folic acid), identifying any physical or mental illness during the study, lack of proper use of drugs or placebo over three days (5) **Intervention:** They are divided into three groups. Group 1: omega3 1 tablet 1000 mg daily, group 2: folic acid 1 tablet 1 mg daily, group 3: placebo 1tablet daily, for three months (6) **Primary outcome measure:**Intensity, duration and frequency of hot flashes

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017011131880N1**

Registration date: **2017-01-24, 1395/11/05**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-01-24, 1395/11/05

Registrant information

Name

masoumeh chamani

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Iran University of Medical Sciences

Expected recruitment start date

2016-11-21, 1395/09/01

Expected recruitment end date

2017-04-21, 1396/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Comparison of the Effect of Omega3 and Folic Acid Oral Tablet on Hot Flashes in Menopausal Women

Public title

The Comparison of the Effect of Omega3 and Folic Acid Oral Tablet on Hot Flashes in Menopausal Women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : Iranian, age 45-60 years, menopause is the normal type have, reporting at least two times hot flashes per day , with literacy being studied components or a family member, body mass index 20 to 30, non receiving hormone therapy , anti-depressants or tranquilizers, supplements and herbal medicines, no known underlying disease (hypertension, diabetes, epilepsy, etc.), the lack of experience of such as relatives died in the last 6 months of stress, separation of spouses and absence of estrogen-dependent cancer, non consumption of more than 2 servings of fish per weeks, insensitivity to fish or fish oil, seafood, avoiding the use of any drugs to improve the symptoms of hot flashes, at least one year and a maximum of three years have menstruation, exercise not more than 2 times a week for 20-30 days, Exclusion criteria: the other drug use during the study, in case of complications or allergic drugs (omega-3 or folic acid), identifying any physical or mental illness during the study, lack of proper use of drugs or placebo over three days

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Triple blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

Randomization: Sample allocation in the case and control group will be conducted randomly and using lottery through numbering 1, 2 and 3 on the cards. The samples will be asked to pick a card. By choosing a card, randomly the sample will be placed in one of the following groups: Group Evening omega3 (1 tablet 1000 mg daily), folic acid (1 tablet 1 mg daily) and placebo groups (1 capsules daily) Blinding: the medicine (omega3 and folic acid) and placebo in the form of similar tablet will be produced by pharmacology advisor. Also putting capsules in the same containers and coding them will be performed by him. And at the end of the study and after analyzing the results, the tablet containers will be decoded. Thus, the samples are not aware of the contents of the medicine containers. As well as

researchers and statistical analysts are not aware of the contents of the medicine containers and each groups What medications are taking. So, the study is a triple-blind

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Iran University of Medical Sciences

Street address

School of Nursing and Midwifery, Yasemi Rashid Street, Valiasr Street, Tehran

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Postal code

1996713883

Approval date

2016-08-08, 1395/05/18

Ethics committee reference number

IR. IUMS. REC 1395 - 9311373012

Health conditions studied**1****Description of health condition studied**

menopause

ICD-10 code

N95.1

ICD-10 code description

Menopausal and female climacteric states

Primary outcomes**1****Description**

The severity of hot flashes

Timepoint

Before the intervention, one month and two months and three months after intervention

Method of measurement

Daily hot flash diary form

Secondary outcomes**1****Description**

duration of hot flashes

Timepoint

Before the intervention, one month and two months and three months after intervention

Method of measurement

Daily hot flash diary form

2

Description

Frequency hot flashes

Timepoint

Before the intervention, one month and two months and three months after intervention

Method of measurement

Daily hot flash diary form

Intervention groups

1

Description

Intervention group: omega3 1 tablet 1000 mg daily, group folic acid 1 tablet 1 mg daily. omega3 is made zahravi, folic acid made Shahid Beheshti University of Medical Science in the School of Pharmacy

Category

Placebo

2

Description

Control group: placebo 1 tablet daily for 3 months, made School of Pharmacy Shahid, Beheshti University of Medical Sciences

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

north west public health centers affiliated Iran University of Medical Sciences

Full name of responsible person

Zahra Keshavarzian

Street address

60/5000 Ministers street, opposite the cinema release, North West of Tehran Health Center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Iran University of Medical Sciences

Full name of responsible person

Morteza Naser Bakhat

Street address

Iran University of Medical Sciences, next to Milad Tower, Hemmat Highway, Tehran

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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

Vice chancellor for research, Iran 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

Iran University of Medical Sciences, School of Nursing and Midwifery

Full name of responsible person

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Position

Master student of midwifery

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