Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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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 20-30Dqyqh,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
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
City
tehran
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 affliated Iran University of Medical Sciences
Full name of responsible person
Zahra Keshavarzian
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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

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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