Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effect of Omega3 on Vasomotor Disorders in Menopausal Women

Protocol summary

Summary

The purpose of this triple blind placebo controlled randomized is to investigate the effect of Omega3 in the treatment of hot flash. Study population are 80 menopausal women (40 women in each intervention and control group) are referred to Public Health centers affiliated to Zanjan University of Medical Sciences & Health Services, were randomly assigned to receive omega3 or placebo 1000 mg capsules once daily for 2 months. Main outcome measures are frequency and severity of Hot flash and Night sweating measured by Questionnaire of full medical history and Diary Card of frequency and severity of hot flash and night sweat and Questionnaire of Food Frequency before and after the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138903224253N1**
Registration date: **2010-07-01, 1389/04/10**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-07-01, 1389/04/10

Registrant information

Name

Razieh Moghadam

Name of organization / entity

The International Branch of Shahid Beheshti University of Medical Sciences & Health Public

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

The International Branch of Shahid Beheshti University of Medical Sciences & Health Services

Expected recruitment start date

2010-07-01, 1389/04/10

Expected recruitment end date

2010-12-01, 1389/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Omega3 on Vasomotor Disorders in Menopausal Women

Public title

Effect of Omega3 on Hot flash

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : Iranian nationality, being literate, age 45-60 years, post menopausal females (no periods for over 12 months), reporting at least two times hot flashes per day Exclusion criteria: Receiving hormone therapy , having any known diseases such as (diabetes, cardiovascular diseases, hypertension, thyroid diseases, liver diseases, blood diseases, cancer, reflux), consumption of drugs such as anticoagulants, sedatives, alfa-adrenergic agonists such as clonidine, supplements such as soya, black cohosh, flaxeed, prime rose oil, or vitamin E, consumption of more than 2 servings of fish per weeks, hypersensitivity to fish or fish oil

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: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Triple blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
The International Branch of Shahid Beheshti University of Medical Sciences & Health services
Street address
No 19, Shahid Abaspoorst, next to Shahid Hammat Bridge
City
Tehran
Postal code
3693-14155
Approval date
empty
Ethics committee reference number
901/116

Health conditions studied

1

Description of health condition studied
Vasomotor Disorders
ICD-10 code
Z76.9
ICD-10 code description
Person encountering health services in unspecified circumstances

Primary outcomes

1

Description
Hot flash and Night sweat
Timepoint
Two weeks before study and everyday during the study period
Method of measurement
Questionnaires, Dairy cards

Secondary outcomes

1

Description
Kinds of food concumption and Food frequency
Timepoint
Before, at the middle, and after the intervention
Method of measurement
Food Frequency Questionairre

Intervention groups

1

Description
Omega3 Capsules, 1mg, daily, for two months
Category
Treatment - Drugs

2

Description
Placebo cap, 1mg, daily, for two months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Public Health centres affiliated to Zanjan University of Medical Sciences
Full name of responsible person
Razieh Moghadam
Street address
No 147, Bahar Ave., Sady Shomaly Street, Zanjan, Iran
City
Zanjan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
The International Branch of Shahid Beheshti Univercity of Medical Sciences & Health services
Full name of responsible person
Dr. Ghanati, Research Manager
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No 19, Shahid Abaspoorst, next to Shahid Hammat

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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

The International Branch of Shahid Beheshti Univercity of Medical Sciences & Health services

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

The International Branch of Shahid Beheshti University of Medical Sciences & Health Services

Full name of responsible person

Razieh Moghadam

Position

Midwifery Master student of the International Branch of Shahid Beheshti University of Medical Scienc

Other areas of specialty/work

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Person responsible for updating data

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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