

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of Omega3 on Vasomotor Disorders in Menopausal Women

#### Protocol summary

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##### 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.

##### 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

#### 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

+98 24 1424 3345

###### Email address

##### 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 consumption and Food frequency

#### Timepoint

Before, at the middle, and after the intervention

#### Method of measurement

Food Frequency Questionnaire

## 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  
University of Medical Sciences & Health services

##### Full name of responsible person

Dr. Ghanati, Research Manager

##### Street address

No 19, Shahid Abaspoorst, next to Shahid Hammat

Bridge  
**City**  
Tehran  
**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 University 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****Street address**

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## Person responsible for scientific inquiries

### Contact

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**Full name of responsible person**

Giti Ozgoli  
**Position**  
Academic faculty member  
**Other areas of specialty/work**  
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## Person responsible for updating data

### Contact

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**Position**

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kian.ghanati@yahoo.com

**Web page address**

## 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*