

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jun 2026

### The evaluation of omega3 effect versus placebo on hot flash in peri-menopausal women

#### Protocol summary

##### Summary

The objective of this study is to compare the effects of omega-3 and placebo in relieving menopausal symptoms, especially hot flash. In this double blind randomized clinical trial, Sixty healthy women suffering from hot flash with their menopause beginning about 12 months (6 to 18 months) were assigned to placebo and omega-3 groups, to evaluate hot flash severity and rate of attacks. Patients took the drug daily for 3 months. (omega-3, 1000mg daily and placebo with the same appearance once daily) and the severity and rate of attacks compared before beginning of treatment and monthly during the study and then at the 3rd and sixth month after ending the treatment.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201102165737N1**

Registration date: **2011-04-06, 1390/01/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2011-04-06, 1390/01/17

##### Registrant information

###### Name

Azadeh Rezaee

###### Name of organization / entity

Tehran University of Medical Sciences and Health Services

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8824 6926

##### Email address

azadehrezae@royaninstitute.org

##### Recruitment status

**Recruitment complete**

##### Funding source

Tehran University of Medical Sciences and Health Services

##### Expected recruitment start date

2009-05-22, 1388/03/01

##### Expected recruitment end date

2009-11-21, 1388/08/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The evaluation of omega3 effect versus placebo on hot flash in peri-menopausal women

##### Public title

The effect of omega3 on hot flash

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: women aged 45 to55 years, BMI=20-30, FSH>20, Having 2 hot flash attack per day  
Exclusion criteria: using clonidin, anti depressant agents, tamoxifen, raloxifen, antibiotics, anti acids, soya, vit E, or anti coagulants, any hormone therapy in the last 6 month, fish allergy

##### Age

From **45 years** old to **55 years** old

##### Gender

Female

##### Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 60

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Tehran University of Medical Sciences and Health Services

##### Street address

Pardis unit/Shahid Hemat high way/Tehran

##### City

Tehran

##### Postal code

#### Approval date

2009-04-29, 1388/02/09

#### Ethics committee reference number

13273

## Health conditions studied

### 1

#### Description of health condition studied

Hot flash

#### ICD-10 code

r50,r51,r5

#### ICD-10 code description

General symptoms and signs

## Primary outcomes

### 1

#### Description

rate of hot flash

#### Timepoint

before intervention/after each month of intervention/3,6month after intervention ended

#### Method of measurement

counting number of hot flash attack

### 2

#### Description

severity of hot flash

#### Timepoint

before intervention/after each month of intervention/3,6 month after intervention ended

#### Method of measurement

menopause rating scale(MRS)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention: omega3, Capsule 1000mg, oral, daily,for 3 months

#### Category

Treatment - Drugs

### 2

#### Description

Control: placebo, Capsule, oral, daily, for 3 months

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Akbar Abadi Hospital

##### Full name of responsible person

Azadeh Rezaee/Resident of G&O

##### Street address

Akbar Abadi Hospital/Molavi/Teran/Iran

##### City

Tehran

### 2

#### Recruitment center

##### Name of recruitment center

Rasule Akram Hospital

##### Full name of responsible person

Azadeh Rezaee

##### Street address

Rasule Akram Hospital/Niyayesh/Satar khan/Tehran/Iran

##### City

Tehran

## Sponsors / Funding sources

# 1

## Sponsor

### Name of organization / entity

Tehran University of Medical Sciences and Health Services

### Full name of responsible person

Dr. Seyed Ali javad Musavi (Head master of research affairs)

### Street address

Pardise Hemat Unit/ Shahid Hemat High way/Tehran/ Iran

### City

Tehran

## Grant name

## Grant code / Reference number

## Is the source of funding the same sponsor organization/entity?

Yes

## Title of funding source

Tehran University of Medical Sciences and 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

Tehran University of Medical sciences and Health Services

#### Full name of responsible person

Azadeh Rezaee

#### Position

Resident of Gynecology and Obstetric

#### Other areas of specialty/work

#### Street address

Tehran University of Medical sciences and Health Services/Shahid Hemat High way/Tehran/IRAN

#### City

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#### Postal code

#### Phone

+98 21 8860 2202

#### Fax

#### Email

www.tums.ir

#### Web page address

## Person responsible for scientific inquiries

### Contact

### Name of organization / entity

Tehran University of Medical Sciences and Health Services

### Full name of responsible person

Azadeh Rezaee

### Position

Resident of Gynecology and Obstetric

### Other areas of specialty/work

### Street address

Tehran university of Medical Sciences and Health Services/Shahid Hemat High way/Tehran/Iran

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## Person responsible for updating data

### Contact

#### Name of organization / entity

Tehran University of Medical Sciences and Health Services

#### Full name of responsible person

Azadeh Rezaee

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#### 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*