Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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)

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+98 21 8824 6926

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azadehrezaee@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 Genycology and Obstetric

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

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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