Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jun 2026

Evaluation of the effect of Omega-3 fatty acids on the treatment of premenstrual syndrome

Protocol summary

Summary

Objective: to evaluate the effect of Omega-3 fatty acids on the treatment of premenstrual syndrome. Method: A randomized double blind controlled trial was performed on 180 eligible women. The eligible women were randomly assigned into two groups. 120 women finally finished the study. In the case group (Omega-3 group), Omega-3 in a dose of 2 gram (2 one gram pearls), and in the control group (placebo group) 2 placebo pearls, which were completely similar to Omega-3 pearls, were prescribed. The severity and duration of each of the symptoms were compared in both groups 1.5 and 3 months after the beginning of treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138808122624N2**
Registration date: **2010-05-25, 1389/03/04**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-05-25, 1389/03/04

Registrant information

Name

Maryam Kashanian

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

maryamka@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2008-08-30, 1387/06/09

Expected recruitment end date

2009-02-27, 1387/12/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Omega-3 fatty acids on the treatment of premenstrual syndrome

Public title

Effect of Omega-3 fatty acids on premenstrual syndrome

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Age between 20-45, educational status of more than diploma, regular & normal menstruation, BMI= 19-26, and having premenstrual syndrome.
Exclusion criteria: pregnancy and lactation, primary and secondary amenorrhea, any history of psychological disorders, any drug use, using contraceptive pills, allergy to omega-3, history of coagulopathy, and using food supplements, history of dramatic events like marriage, death of relatives and surgery during last 3 months.

Age

From **20 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size
Target sample size: **123**

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
Iran University of Medical Sciences

Street address
Iran University of Medical Sciences, Hemmat Highway

City
Tehran

Postal code

Approval date
2008-02-05, 1386/11/16

Ethics committee reference number
5869

Health conditions studied

1

Description of health condition studied
Premenstrual syndrome

ICD-10 code
n94.3

ICD-10 code description
Premenstrual tension syndrome

Primary outcomes

1

Description
somatic sign of premenstrual syndrome

Timepoint
1.5 and 3 months later

Method of measurement
questionnare

2

Description
psychiatric sign of premenstrual syndrome

Timepoint
1.5 & 3 months

Method of measurement
questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Omega3 prescription, 2 gram/daily

Category
Treatment - Drugs

2

Description
Plecebo prescription

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
hospitals of Iran University of Medical Sciences

Full name of responsible person

Street address

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Investigator

Full name of responsible person
Dr. Maryam Kashanian

Street address
Iran University of Medical Sciences, Faculty of Medicine

City
Tehran

Grant name

Grant code / Reference number

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

Title of funding source
Investigator

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
Iran University of Medical Sciences

Full name of responsible person
Maryam Kashanian

Position
Associate professor

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