

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

The effect of omega-3 fatty acid and Perforan on severity of symptoms in premenstrual syndrome

Protocol summary

Summary

The aim of this study is to assess the severity of the symptoms of the premenstrual syndrome and to compare the therapeutic effects of Omega-3 fatty acid and perforan on the symptoms of premenstrual syndrome. It was studied on three groups with 180 students of the dormitory of Isfahan University in Iran. At first step, they filled a questionnaire about their symptoms for two menstrual cycles. Mild and moderate premenstrual syndrome, Regular 24-35 days menstrual cycles, lack of having mental illness and physical and endocrine disease or having allergy to fish or sunlight are some criteria for entering to this study. Unwillingness to continue the study and appearing any kind of disease in during of the study such as endocrine disease, appearing any complications or drug allergy, lack of taking drugs in the first cycle for one week frequently and lack of taking drugs for two days in second and third cycles are some criteria for stopping the study. The students of this study are divided randomly to three groups include of omega 3 fatty acid (1000 mg) group, perforan group (480 mg) and placebo control group. Every student in this study takes drugs during three subsequent cycles so that she takes two capsules daily in the first cycle for one month and in second and third cycles she takes them from eight days before menstruation to two days after it and records the severity of the symptoms of her menstruation in the questionnaire of the symptoms. The result of this Study for the students is the reduction of the severity of mental, physical and behavior symptoms of premenstrual syndrome.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201107262751N3**

Registration date: **2012-03-19, 1390/12/29**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-03-19, 1390/12/29

Registrant information

Name

Masoomeh Kheirkhah

Name of organization / entity

Iran university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8247 1000

Email address

kheirkhah@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2011-12-31, 1390/10/10

Expected recruitment end date

2012-05-30, 1391/03/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of omega-3 fatty acid and Perforan on severity of symptoms in premenstrual syndrome

Public title

Comparison of Perforan and omega-3 on severity of premenstrual syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Regular menstrual cycles 24-35 days, 18-35 years of age and unmarried, non-psychotic mental illness, lack of physical illnesses including endocrine diseases known as non-hormonal drugs, anticoagulant, antidepressants, supplements and herbal medicine, not taking any medication for the treatment of premenstrual syndrome, No alcohol or drugs, sensitivity to the sun and sea food, relatives who died in the last 3 months, surgery in the last 3 months. Exclusion criteria: any disease endocrine disease during the study, having severe premenstrual syndrome, married during the study, Unwillingness to continue the study, If complications or allergic to a drug or other drug use, stop taking the medication for a week in regular cycles and irregular drug consumption in the second and third cycles for two days.

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **180**

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

Street address

5th Floor of the Central Organization, Tehran
University of Medical Sciences, Ghods St., Keshavarz
Blvd

City

Tehran

Postal code

1417653761

Approval date

2011-06-18, 1390/03/28

Ethics committee reference number

1749

Health conditions studied

1

Description of health condition studied

Premenstrual syndrome

ICD-10 code

F59

ICD-10 code description

Unspecified behavioural syndromes associated with physiological disturbances and physical factors

Primary outcomes

1

Description

Reduction in physical symptoms (headache, breast swelling and tenderness, back pain, abdominal pain, muscle pain, weight gain, swelling of extremities, nausea, diarrhea or constipation)

Timepoint

One month, two months, three months after intervention

Method of measurement

Questionnaire

2

Description

Reduction in behavioral symptoms (fatigue, lack of energy, insomnia, difficulty concentrating, increased appetite)

Timepoint

One month, two months, three months after intervention

Method of measurement

Questionnaire

3

Description

Reduction in mood symptoms (irritability and restlessness, anxiety and impatience, anger, depression and sadness, crying for no reason, feeling alone)

Timepoint

One month, two months, three months after intervention

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Side effects of drugs

Timepoint

Three months after the intervention

Method of measurement

Questionnaire

Intervention groups

1

Description

Placebo capsules, 1000 mg, 2 times a day, orally for 3 months

Category

Treatment - Drugs

2

Description

Perforun Capsules, 240 mg, 2 times a day, orally for 3 months

Category

Treatment - Drugs

3

Description

Fatty acid capsules three thousand milligrams, twice daily for 3 months, orally

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Esfahan non-medical students dormitories

Full name of responsible person

Kobra Abbasinya, Midwifery master of science student

Street address

City

Esfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Masoud Younesian

Street address

5th Floor of the Central Organization, Tehran
University of Medical Sciences, Ghods St, Keshavarz
Blvd

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

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran university of medical sciences

Full name of responsible person

Masoomeh Kheirkhah

Position

University Lecturer, Master of Midwifery

Other areas of specialty/work

Street address

5th Floor of the Central Organization, Tehran
University of Medical Sciences, Ghods St, Keshavarz
Blvd

City

Tehran

Postal code

Phone

+98 21 8163 3575

Fax

Email

kheirkhah@iums.ac.ir

Web page address

Person responsible for updating data

Contact

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