Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)
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+98 21 8247 1000
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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 Scinces

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
Premenstural 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
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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