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

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
None

Sample size
Target sample size: 123

Randomization (investigator’s opinion)
Randomized

Randomization description
None

Blinding (investigator’s opinion)
Double blinded

Blinding description
None

Placebo

Recruitment status
Recruitment complete

Funding source
Investigator
### 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**: 1386/11/16
- **Approval date**: 2008-02-05
- **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**: questionnaire

#### 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**: Placebo prescription
- **Category**: Placebo

### Recruitment centers

#### 1
- **Recruitment center**
  - **Name of recruitment center**: hospitals of Iran University of Medical Sciences
  - **Full name of responsible person**: Dr. Maryam Kashanian
  - **Street address**: Iran University of Medical Sciences, Faculty of Medicine
  - **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**: empty
  - **Type of organization providing the funding**: empty
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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