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

**Recruitments 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**
None

**Sample size**
Target sample size: 123

**Randomization (investigator's opinion)**
Randomized

**Randomization description**

**Blinding (investigator's opinion)**
Double blinded

**Blinding description**
Placebo
### 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**  
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   **City**  
   Tehran

### Sponsors / Funding sources

1. **Sponsor**  
   Name of organization / entity  
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   **City**  
   Tehran  
   **Grant name**  
   ---------  
   **Grant code / Reference number**  
   0000  
   **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
Person responsible for general inquiries

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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