Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison the Effect of Vit E, Vit B6, Calcium and Omega-3 on Treatment of Premenstrual Syndrome In Student of Islamic Azad University Sari Branch

Protocol summary

Summary

Objectives: To Compare the Effect of Vitamins E, B6, Calcium and Omega-3 Fatty Acids in the Treatment of Severe Mental and Physical Symptoms of Premenstrual Syndrome. Design: In this Clinical Trial, Female Students of Islamic Azad University of Sari Branch Will be Selected On the Basis of Inclusion and Exclusion Criteria of the Study and Will Fill in the Rosignol Bonlender's Check list of the Standard Symptoms for 3 Months to Diagnose the Premenstrual Syndrome. 200 Female Patients With Moderate and Severe Forms of the Syndrome are Randomly Assigned to Five Treatment Groups. Setting & Conduct: First Group Received 1g Calcium, During Last 7 Days of the Cycle for Three Months, the Second Group Took 100 mg of Vitamin E Daily for Three Months, the Third Group Received 1 g Capsule of Fish Oil Daily for Three Months, the Forth Group Received 40 mg of Vitamin B6 Daily for Three Months, and the Last Group Received Daily One Tablet of Placebo for Three Months. In This Three Months Period, Rosignol Bonlender's Check List of Symptoms was Also Filled. Participants With Main Inclusion and Exclusion Criteria: Single Girls With Age From 18 to 30 Years With Regular Menstrual Cycles or Cycles Between 21-35 Days Were Included in the Study. And Those Who Were Breast Feeding, Taking Hormonal Contraceptive pills, Had a History of Mental Illnesses Such as Depression, Had Traumatic Problems Within 2 Months Ago or Took Antidepressants or Herbal Within 6 Months were Excluded From the Study. Interventions: Vitamin E, Vitamin B6, Calcium, Omega-3 Fatty Acids and Placebo. Outcome Variables: Severity of Mental Symptoms, Severity of Physical Symptoms, Severity of Premenstrual Syndrome Before and After the Treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012123010705N1**
Registration date: **2013-01-22, 1391/11/03**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-01-22, 1391/11/03

Registrant information

Name
Mandana Zafari
Name of organization / entity
Islamic Azad Universirt Sari Branch
Country
Iran (Islamic Republic of)
Phone
+98 15 1229 2263
Email address
mandanazafari@iausari.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Islamic Azad University Sari Branch, Darya Bolvar, Khazar Square, Sari, Mazandaran, Iran.

Expected recruitment start date

2011-03-20, 1389/12/29

Expected recruitment end date

2012-03-19, 1390/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison the Effect of Vit E, Vit B6, Calcium and Omega-3 on Treatment of Premenstrual Syndrome In Student of Islamic Azad University Sari Branch

Public title
Effect of Vit E, Vit B6, Calcium and Omega-3 on Treatment of Premenstrual Syndrome.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion Criteria: Single Girls, Aged Between 18-30 Years Old, Having Regular Menstrual Cycles, Duration of the Cycle Between 21-35 Days, Having Moderate and Sever Form of Premenstrual Syndrome According to the Standard Questionnaire of Rosignol Bonlender. Exclusion Criteria: Breast Feeding, Use of Oral Contraceptive Pills, Having a History of Psychological Diseases Such as Depression, Traumatic Problems During the Past Two Months, Taking Antidepressants and Herbal Drugs 6 Months Ago.

Age
From **18 years** old to **30 years** old

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **200**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

1

Registry name
-

Secondary trial Id
-

Registration date
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethic Committee of Islamic Azad University Sari Branch

Street address
Vice Chancellor for Research, Islamic Azad University Sari Branch, Sari, Mazandaran, Iran

City
Sari

Postal code
48161-19318

Approval date
2012-09-22, 1391/07/01

Ethics committee reference number
1391-4

Health conditions studied

1

Description of health condition studied
Premenstrual syndrom

ICD-10 code
N94.3

ICD-10 code description
Premenstrual Tension Syndrome

Primary outcomes

1

Description
Severity of Premenstrual Syndrom

Timepoint
Before and Three Months After Treatment

Method of measurement
Rosignol Bonlender Questionnair & Checklist

Secondary outcomes

1

Description
Severity of Physical Symptoms of Premenstrual Syndrom

Timepoint
Before Treatment and Three Months After Treatment

Method of measurement
Rosignol Bonlender Questionnaire

2

Description
Severity of Psycological Symptoms of Premenstrual Syndrom

Timepoint
Before Treatment and Three Months After Treatment

Method of measurement
Rosignol Bonlender Questionnaire

3

Description
Severity of Premenstrual Syndrom

Timepoint
Before Treatment and Three Months After Treatment

Method of measurement
Rosignol Bonlender Questionnaire

Intervention groups

1

Description
Vit E : Receiving vit E 100 mg/day For Three Months
Category
Treatment - Drugs

2

Description
Calcium 1 gram: Receiving 1 gram Calcium During 7 Days End of Cycle for Three Months.
Category
Treatment - Drugs

3

Description
Capsule of Fish Oil: Receiving 1 gram Capsule Every Day for Three Months
Category
Treatment - Drugs

4

Description
Vit B6 : Receiving 40 mg/ Day for Three Months
Category
Treatment - Drugs

5

Description
Placebo: Receiving 1 / Day for Three Months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Dormitory & Colleges of Islamic Azad University Sari Branch, Darya Bolvar, Khazar Square, Sari, Maz
Full name of responsible person
Hamed Samadi
Street address
Islamic Azad University Sari Branch, Darya Bolvar, Khazar Squar, Sari, Mazandaran, Iran.
City
Sari

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Islamic Azad University Sari Branch, Darya Bolvar, Khazar Square, Sari
Full name of responsible person
Hamed Samadi
Street address
Vice Chancellor for Research, Islamic Azad University Sari Branch, Darya Bolvar, Khazar Square, Sari, Mazandaran, Iran
City
Sari
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research, Islamic Azad University Sari Branch, Darya Bolvar, Khazar Square, Sari
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
Islamic Azad University Sari Branch
Full name of responsible person
Mandana Zafari
Position
PhD Student of Thalassemi, Faculty Member
Other areas of specialty/work
Street address
Islamic Azad University Sari Branch, Darya Bolvar, khazar Squar, Sari, Mazandaran, Iran
City
Sari
Postal code
4816715691
Phone
+98 15 1229 2263
Fax
Email
mandanazafari@yahoo.com; mandanazafari@iausari.ac.ir
Web page address

Person responsible for scientific

inquiries

Contact

Name of organization / entity
Islamic Azad University Sari Branch

Full name of responsible person
Mandana Zafari

Position
PhD Student of Thalassemia

Other areas of specialty/work

Street address
Islamic Azad University Sari Branch, Darya Bolvar, Khazar square, Sari, Mazandaran, Iran

City
Sari

Postal code
1816715691

Phone
+98 15 1229 2263

Fax

Email
mandanazafari@yahoo.com; mandanazafari@iausari.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University Sari Branch

Full name of responsible person
Mandana Zafari

Position
PhD Student of Thalassemia/ Faculty Member

Other areas of specialty/work

Street address
Islamic Azad University Sari Branch, Darya Bolvar, Khazar Square, Sari, Mazandaran, Iran

City
Sari

Postal code
48167-15691

Phone
+98 15 1229 2263

Fax

Email
mandanazafari@yahoo.com ; mandanazafari@iausari.ac.ir

Web page address

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