Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of the effect of Primerose oil and Vitamin B6 versus placebo on premenstrual syndrome in girl college students: a double blind randomized clinical trial

Protocol summary

Summary

Objectives: To compare the effect of Primerose oil and Vitamin B6 versus placebo on premenstrual syndrome in girl college students. Design: a double blind randomized clinical trial. Setting and conduct: The eligible girl college students with premenstrual syndrome who will educate in Hamadan University of Medical Sciences during the study period will be enrolled into the trial. Inclusion criteria: age of 18 to 35 years; having regular menstrual cycle with 21 to 35 days interval. Exclusion criteria: physical disease or using medications; psychological disease; using anti-depression drugs during past months; using hormonal drugs or vitamins. Intervention group: (a) Primerose oil capsule 1000 mg twice a day from 14 days before menstruation to 5 days after menstruation for two consecutive cycles; (b) Vitamin D capsule 40 mg twice a day from 14 days before menstruation to 5 days after menstruation for two consecutive cycles. Control group: Placebo capsule twice a day from 14 days before menstruation to 5 days after menstruation for two consecutive cycles Primary outcome: severity of symptoms of premenstrual syndrome before intervention and 1 and 2 months after intervention using standard diagnostic questionnaire for premenstrual syndrome. Randomization: The patients will be randomly assigned to intervention and control groups using block randomization. Blinding: Participants will be unaware of the type of intervention. The examiner who will examine the patients will not be aware of the intervention. Therefore, the trial will be run as double blind.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201610289014N127**

Registration date: **2016-10-31, 1395/08/10**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-10-31, 1395/08/10

Registrant information

Name

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Name of organization / entity

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Country

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2016-11-21, 1395/09/01

Expected recruitment end date

2017-11-22, 1396/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Primerose oil and Vitamin B6

versus placebo on premenstrual syndrome in girl college students: a double blind randomized clinical trial

Public title
Comparison of the effect of Primerose oil and Vitamin B6 versus placebo on premenstrual syndrome in girl college students
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: age of 18 to 35 years; having regular menstrual cycle with 21 to 35 days interval. Exclusion criteria: physical disease or using medications; psychological disease; using anti-depression drugs during past months; using hormonal drugs or vitamins.
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: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
Randomization: The patients will be randomly assigned to intervention and control groups using block randomization. Blinding: Participants will be unaware of the type of intervention. The examiner who will examine the patients will not be aware of the intervention. Therefore, the trial will be run as double blind.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Hamadan University of Medical Sciences
Street address
Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Postal code
6517838695
Approval date
2016-10-08, 1395/07/17
Ethics committee reference number
IR.UMSHA.REC.1395.321

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
severity of symptoms of premenstrual syndrome
Timepoint
before intervention and 1 and 2 months after intervention
Method of measurement
using standard diagnostic questionnaire for premenstrual syndrome

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Primerose oil capsule 1000 mg twice a day from 14 days before menstruation to 5 days after menstruation for two consecutive cycles
Category
Treatment - Drugs

2

Description
Intervention group: Vitamin D capsule 40 mg twice a day from 14 days before menstruation to 5 days after menstruation for two consecutive cycles
Category
Treatment - Drugs

3

Description
Control group: Placebo capsule twice a day from 14 days before menstruation to 5 days after menstruation for two consecutive cycles
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Hamadan University of Medical Sciences
Full name of responsible person
Arezoo Shayan
Street address
Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences
Full name of responsible person
Dr Saeid Bashirian
Street address
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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 the Technology, Hamadan 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
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Person responsible for updating data

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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