

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

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

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

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

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

Name of organization / entity

School of Nursing and Midwifery

Full name of responsible person

Arezoo Shayan

Position

Midwife

Other areas of specialty/work**Street address**

School of Nursing and Midwifery, Hamadan University

of Medical Sciences, Shahid Fahmideh Ave.

City

Hamadan

Postal code**Phone**

+98 81 3838 0572

Fax**Email**

arezoo.shayan2012@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

School of Nursing and Midwifery

Full name of responsible person

Arezoo Shayan

Position

Midwife

Other areas of specialty/work**Street address**

School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

City

Hamadan

Postal code**Phone**

+98 81 3838 0572

Fax**Email**

arezoo.shayan2012@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Department of Epidemiology

Full name of responsible person

Dr Jalal Poorolajal

Position

Associate Professor

Other areas of specialty/work**Street address**

School of Public Health, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0090

Fax**Email**

poorolajal@umsha.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