

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

The effects of calcium and vitamin B1 supplementation on premenstrual syndrome (PMS) in female university students: A randomized clinical controlled trial

Protocol summary

Summary

The aim of the study is to determine the effects of calcium and vitamin B1 supplementation on premenstrual syndrome (PMS) in female university students. The study is a double-blind placebo-controlled randomized clinical trial and subjects are 200 female students of Ilam University of Medical Sciences. Students who experience at least 3 symptoms of PMS questionnaire's criteria with moderate and severe intensity during 3 consecutive period cycles and also who have at least 5 signs of the DMS-IV criteria for premenstrual dysphoric disorder (PMDD) will be recruited. The age range of 18 to 30 years and having regular menstruation cycle with 24 to 35 days intervals are among another inclusion criteria. Exclusion criteria include having any history of physical and mental illnesses; consuming any drugs such as anti-convulsants and anti-depressants; consuming multivitamin, vitamin B1 and calcium supplements during last 3 months. The intervention duration is 2 months and subjects will randomly assigned into 4 groups of 54 students as follow: group1: receiving one tablet of 500 mg calcium carbonate per day; group 2: receiving one tablet of 100 mg vitamin B1 per day; group 3: receiving one tablet of 500 mg calcium carbonate and one tablet of 100 mg vitamin B1 per day; group 4: receiving one placebo tablet containing 1 mg of starch powder per day. Primary outcome of the study is the change in the score of the PMS' questionnaire and secondary outcome is the change in the score of the PMDD's questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016011810333N3**
Registration date: **2016-02-13, 1394/11/24**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-02-13, 1394/11/24

Registrant information

Name

Nasrin Sharifi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5562 0608

Email address

sharifi.n@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Ilam University of Medical Sciences

Expected recruitment start date

2016-01-21, 1394/11/01

Expected recruitment end date

2016-03-20, 1395/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of calcium and vitamin B1 supplementation on premenstrual syndrome (PMS) in female university students: A randomized clinical controlled trial

Public title

The effects of calcium and vitamin B1 supplementations on premenstrual syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: The age ranges of 18 to 30 years; having body mass index between 18.5 to 30 kg/m²; having regular menstrual cycle with 24 to 35 days interval; experiencing at least 3 symptoms of PMS questionnaire's criteria with moderate and severe intensity during 3 consecutive period cycles; having at least 5 signs of the DMS-IV criteria for premenstrual dysphoric disorder
Exclusion criteria: having any history of physical and mental illnesses; consuming anti-convulsants; consuming anti-depressants; consuming hormones and oral contraceptives; consuming multivitamin, vitamin B1 and calcium supplements during last 3 months.

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)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ilam University of Medical Sciences

Street address

Ilam University of Medical Sciences, Pajoohesh Blvd.

City

Ilam

Postal code

Approval date

2015-12-08, 1394/09/17

Ethics committee reference number

IR.MEDILAM.REC.1394.88

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

Changes in scores of premenstrual syndrome's questionnaire

Timepoint

Before and 2 months after the start of the intervention

Method of measurement

Standard questionnaire for premenstrual syndrome

Secondary outcomes

1

Description

Changes in scores of the premenstrual dysphoric disorder's questionnaire

Timepoint

Before and 2 months after the start of the intervention

Method of measurement

Standard questionnaire for premenstrual dysphoric disorder

Intervention groups

1

Description

Intervention: Tablet contains 500 mg calcium carbonate and tablet contain 100 mg vitamin B1, each once a day for 8 weeks

Category

Treatment - Drugs

2

Description

Intervention: Tablet contains 100 mg vitamin B1, once a day for 8 weeks

Category

Treatment - Drugs

3

Description

Control: Tablet contains 1 mg starch powder, once a day for 8 weeks

Category

Treatment - Drugs

4

Description

Intervention: Tablet contains 500 mg calcium carbonate, once a day for 8 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ilam University of Medical Sciences

Full name of responsible person

Dr. Sepeedeh Zahra Farhang

Street address

Ilam University of Medical Sciences, Pajooresh Blvd.

City

Ilam

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ilam University of Medical Sciences

Full name of responsible person

Dr. Behzad Badakhsh

Street address

Vice Chancellor for Research and Technology, Ilam University of Medical Sciences

City

Ilam

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ilam 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

Ilam University of Medical Sciences

Full name of responsible person

Soheila Samieepour

Position

MSc of Food Sciences and Technology

Other areas of specialty/work

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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