Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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, Pajoohesh 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
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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