

# 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/m<sup>2</sup>; 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**

##### **Street address**

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sarma1364@gmail.com

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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*