

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Jun 2026

### The Effect of Calcium Supplementation on Premenstrual Syndrome of Female students

#### Protocol summary

##### Summary

Premenstrual Syndrome Symptoms of a set of physical, psychological, emotional and behavioral changes that in the luteal phase of the menstrual period occurs. Premenstrual syndrome, impaired communication, disrupting normal activity and sedentary. The aim of this study is to evaluate the effectiveness calcium supplement on premenstrual syndrome of Female students in Hamadan university of medical sciences. This clinical trial study will carry out in sixty four women with premenstrual syndrome in Hamadam university of medical sciences, Hamadan, Iran. Witten informed consent will obtain from all participants. The participants will randomly select to one of two oral treatments groups: Calcium (500mg/day) or Placebo. Demographic Questionnaire and the standard provisional diagnosis of menstruation and premenstrual syndrome, derived from the DSM-IV, is used. Severity of premenstrual syndrome will compare the case and control groups before and after treatment intervention end of two months.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201309296888N4**

Registration date: **2013-12-20, 1392/09/29**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2013-12-20, 1392/09/29

##### Registrant information

###### Name

Fatemeh Shobeiri

###### Name of organization / entity

Hamadan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 1827 6051

###### Email address

shobeiri@umsha.ac.ir

###### Recruitment status

**Recruitment complete**

###### Funding source

Hamadan University of Medical Sciences, Department of Research and Technology

###### Expected recruitment start date

2013-09-23, 1392/07/01

###### Expected recruitment end date

2014-12-20, 1393/09/29

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

The Effect of Calcium Supplementation on Premenstrual Syndrome of Female students

###### Public title

The Effect of Calcium Supplementation on Premenstrual Syndrome of Female students

###### Purpose

Treatment

###### Inclusion/Exclusion criteria

Inclusion criteria: Student; Having premenstrual syndrom; Lack of alleregy to drugs, Exclusion criteria: Women with age below 17 and above 44 years; Pregnancy; Alleregy to drugs

###### Age

From **17 years** old to **44 years** old

###### Gender

Female

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: **64**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics committee

**Street address**

Fahmodeh street, Hamadan Hamadan University of Medical Sciences, Department of Research and Technology

**City**

Hamadan

**Postal code**

**Approval date**

2013-07-24, 1392/05/02

**Ethics committee reference number**

1345

**Health conditions studied**

1

**Description of health condition studied**

Symptoms, signs and abnormal clinical and laboratory findings, not elsewhere classified

**ICD-10 code**

R40-R46

**ICD-10 code description**

Symptoms and signs involving cognition, perception, emotional state and behaviour

**Primary outcomes**

1

**Description**

Premenstrual syndrome

**Timepoint**

Two months

**Method of measurement**

Questionnaire

**Secondary outcomes**

empty

**Intervention groups**

1

**Description**

Intervention group: Prescription oral Calcium (500 mg/daily) for two months.

**Category**

Treatment - Drugs

2

**Description**

Control group: Prescription Placebo for two months.

**Category**

Treatment - Drugs

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Hamadan University of Medical Sciences

**Full name of responsible person**

Fatemeh Shobeiri

**Street address**

Fahmodeh street, Hamadan University of Medical Sciences, Hamadan

**City**

Hamadan

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Hamadan University of Medical Sciences, Department of Research and Technology (Prim

**Full name of responsible person**

saiid Bashirian

**Street address**

Fahmiheh Street, Hamadan University of Medical Sciences, Department of Research and Technology (Primary sponsor)

**City**

Hamadan

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Hamadan University of Medical Sciences, Department of Research and Technology (Prim

**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**

Hamadan University of Medical Sciences

**Full name of responsible person**

Fatemeh Shobeiri

**Position**

Associate professor, Ph.D. of Maternal and child Health

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

Fahmodeh street, Hamadan University of Medical Sciences, Hamadan

**City**

Hamadan

**Postal code****Phone**

+98 81 1838 0150

**Fax****Email**

shobeiri@umsha.ac.ir

**Web page address**

Fahmodeh street, Hamadan University of Medical Sciences, Hamadan

**City**

Hamadan

**Postal code****Phone**

+98 81 1838 0150

**Fax****Email**

shobeiri@umsha.ac.ir

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Hamadan University of Medical Sciences

**Full name of responsible person**

Fatemeh Shobeiri

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**Fax****Email**

shobeiri@umsha.ac.ir

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Hamadan University of Medical Sciences

**Full name of responsible person**

Fatemeh Shobeiri

**Position**

Associated professor, Ph.D. of Maternal and child Health

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