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 Universiy 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
Questionaire

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
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Person responsible for updating data

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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