Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jun 2026

Comparative study of the effect of oral calcium and magnesium on the reduction of PMS

Protocol summary

Study aim
comparison of the effect of oral calcium and magnesium on the reduction of pms

Design
Double-blind clinical trial.

Settings and conduct
204 female students of Shahrekord University of Medical Sciences with a definite diagnosis of PMS were divided into a group of68. The first group was given 1000 mg of oral calcium and the second group was given 300 mg of magnesium daily during one week before menstruation. The third group is followed as a control group. Patients will be examined with a questionnaire and checklist during 3 consecutive periods of menstruation in terms of clinical symptoms. The data will be analyzed after collection and the results will be presented in the form of articles and dissertations

Participants/Inclusion and exclusion criteria
Entry criteria: Entry includes being single, regular and normal menstruation with intervals of 21 to 35 days and a duration of 3-7 days during the past six months, not suffering from known physical and mental diseases and not undergoing any type of treatment in order to alleviate the symptoms of the syndrome. Premenstrual during the study period Non-entry criteria: Not having entry criteria

Intervention groups
Student girls living in the dormitory of Shahrekord University of Medical Sciences who, based on the DSM-V criteria (presence of at least 5 of the disease symptoms listed in the questionnaire within 5 days before the start of monthly bleeding, which are present in at least 3 consecutive periods and within several the day after the bleeding disappears) have PMS

Main outcome variables
premenstrual syndrome

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160709028844N1**
Registration date: **2023-04-26, 1402/02/06**
Registration timing: **retrospective**

Last update: **2023-04-26, 1402/02/06**
Update count: **0**

Registration date
2023-04-26, 1402/02/06

Registrant information

Name
Sheida Shabanian

Name of organization / entity
Shaharekord University of Medical Sciences,

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-11-21, 1397/08/30

Expected recruitment end date
2019-04-19, 1398/01/30

Actual recruitment start date
2018-11-21, 1397/08/30

Actual recruitment end date
2019-04-19, 1398/01/30

Trial completion date
2019-06-20, 1398/03/30

Scientific title
Comparative study of the effect of oral calcium and magnesium on the reduction of PMS

Public title
oral calcium and magnesium on the reduction of pms

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Female students of Shahrekord University of Medical Sciences with definite diagnosis of premenstrual syndrome Not using other treatment methods Willingness to participate in the study Not suffering from known physical and mental diseases single Calendar age 18 to 27 years Regular menstrual cycle of 21 to 35 days Menstruation duration 3-7 days during the last six months In terms of the severity of PMS symptoms, they were matched according to the DSM-V score

Exclusion criteria:
Reluctance to participate in the study Use of other treatment methods

Age
From **18 years** old to **27 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **195**
Actual sample size reached: **204**

Randomization (investigator's opinion)
Randomized

Randomization description
The study was conducted in a double-blind and randomization method using stratified random allocation, so that according to the severity of PMS, the patients were divided into three categories: very severe, moderate to severe, and mild, and in each category, they were randomly assigned to three groups A and B. and C were divided. A total of 204 female students living in the dormitory of Shahrekord University of Medical Sciences with PMS were divided in terms of physical symptoms and psychological symptoms, and as a result, 66 people were in the mild category, 84 people were in the moderate category, and 54 people were in the severe category. The random sequence was obtained through the online randomization program (program address: https://www.sealedenvelope.com/simple-randomiser/v1/lists) And based on the random list, each patient was assigned to one of the groups A, B, and C, respectively. In terms of the severity of premenstrual syndrome, in each group of 68 people, there were an equal number of 22 mild, 28 moderate and 18 severe patients. After filling the consent form, the drugs were prepared by a pharmacologist from Dr. Abedi Pharmaceutical Company and divided into three packages of the same color. And one shape was named with letters A, B and C. Group A contained 1000 mg of calcium, group B contained 300 mg of magnesium, and group C contained selenium as a placebo. The patients and the researcher did not know about the contents of the package.

Blinding (investigator's opinion)
Double blinded

Blinding description
he study was double-blind and the drugs were given to the study subjects in packages of the same shape, A, B, and C, and the patients and the researcher did not know about the contents of the package

Placebo
Used

Assignment
Parallel

Other design features
There is no case

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shahrekord University of Medical Sciences

Street address
No. 4, 36 Yaser Ave Shahrekord Town

City
Shahrekord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
8815754673

Approval date
2018-05-23, 1397/03/02

Ethics committee reference number
IR.SKUMS.REC.1397.033

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
Premenstrual syndrome

Timepoint

The beginning of the study and 1, 2 and 3 months after the study

Method of measurement

PMS diagnostic criteria based on DSM-V

Secondary outcomes

1

Description

Physical and mental symptoms

Timepoint

0 start of study and 1 month, 2 months and 3 months later

Method of measurement

DSM-V

Intervention groups

1

Description

Group A consumed 1000 mg of calcium per day for the study period of 3 cycles from the 15th day of the menstrual cycle or immediately after ovulation to the start of menstrual bleeding, and at the end of the cycle and with the beginning of bleeding, they completed the PSST questionnaire.

Category

Treatment - Drugs

2

Description

Group B consumed 300 mg of magnesium daily for the study period of 3 cycles from the 15th day of the menstrual cycle or immediately after ovulation to the onset of menstrual bleeding, and at the end of the cycle and with the onset of bleeding, they completed the PSST questionnaire

Category

Treatment - Drugs

3

Description

Group C used selenium tablets for placebo for 3 study cycles from the 15th day of the menstrual cycle or immediately after ovulation to the beginning of menstrual bleeding, and at the end of the cycle and with the onset of bleeding, they completed the PSST questionnaire

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

student dormitory

Full name of responsible person

Sheida Shabanian

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rahmatieh .Dormitory for female medical students

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahre-kord University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Sheida Shabanian
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available