

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

The effect of vitamin D supplement consumption compared with the placebo on premenstrual syndrome in young girls

Protocol summary

Summary

Premenstrual syndrome (PMS) consists of a group of physical and mental symptoms related to the menstrual cycle. Those who are suffering from this syndrome are usually affected by these symptoms during the luteal phase of their menstrual cycle. Women with PMS have poorer health-related quality of life and this may result in paying higher health care costs. Several studies have evaluated the role of vitamin D in the prevention and treatment of behavioral and gynecologic disorders that share common feature with PMS, including depression, fibromyalgia and painful menstrual periods. All of these studies indicate an inverse relationship between vitamin D levels and diseases mentioned above. However, the effect of vitamin D in PMS is not clear. Therefore, this study is a double blind randomized clinical trial to determine the effect of vitamin D supplement consumption on premenstrual syndrome in young girls. 146 young girls, aged 18-30 years old with PMS, who are eligible for this study will be recruited from girl's dormitories of Iran University of Medical Sciences (IUMS). Informed consent form will be completed by each participant at the beginning of this single center study. Participants will be divided in two groups randomly, participants in intervention group, receiving a 2000IU vitamin D tablet and in control group receiving a placebo contained maltodextrin every other day for 12 weeks. At the beginning and end of study, blood 25(OH)-D3 levels will be measured and the severity of the syndrome before menstrual cycle will be evaluated by questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201510092365N10**

Registration date: **2016-01-04, 1394/10/14**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-01-04, 1394/10/14

Registrant information

Name

Mohammad Reza Vafa

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 8670 4734

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vitamin D supplement consumption compared with the placebo on premenstrual syndrome in young girls

Public title

The effect of vitamin D supplement consumption compared with the placebo on premenstrual syndrome in young girls

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Aged 18-30 years old; BMI 18.5-34.9 kg/m²; 25(OH) D<40 ng/ml; Normal menstrual cycle; Young girls having PMS according to PSST questionnaire. Exclusion criteria: Acute disease; Any event that effect on mental status; Migration.

Age

From **18 years** old to **30 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **146**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

Randomization and Blinding: Participants will allocated randomly using a random number table; for this, a study leader who is not involve in study protocol will create the randomization list assigning participants to the vitamin D or the placebo group. Fifteen vitamin D or placebo tablets are placed into 146 unlabeled identical containers; three containers per each subject are provided for treatment during three 4-week periods. The study leader will label these containers with participant numbers using the randomization list. Compliance with treatment is assessed by pill counts. For this, all participants return their three containers at the end of the each 4-week interval.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

School of Public Health, Iran University of Medical Sciences

Street address

School of Public Health, Iran University of Medical Sciences, Hemat express way, Tehran

City

Tehran

Postal code**Approval date**

2015-09-22, 1394/06/31

Ethics committee reference number

ir.iums.rec.1394.26528

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**

Severity of premenstrual syndrome

Timepoint

Before and 12 weeks after intervention

Method of measurement

PSST Questionnaire

Secondary outcomes**1****Description**

Serum 25(OH)-D3

Timepoint

Before and 12 weeks after intervention

Method of measurement

Laboratory Kit (EUROIMMUN; Germany)

Intervention groups**1****Description**

Intervention group: Consume 1 pill 2000 IU vitamin D (Schiff; made in USA) every other day for 12 weeks

Category

Treatment - Drugs

2**Description**

Control group: Consume 1 pill placebo of vitamin D contained maltodextrin ("Roshd" Pharmaceutical Incubation Center of Tehran University of Medical Sciences) every other day for 12 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Girl's Dormitories of Iran University of Medical of Sciences

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor of Research, Iran University of Medical Sciences

Full name of responsible person

Dr Ali Javadmoosavi

Street address

Vice Chancellor of Research, Iran University of Medical Sciences, Hemat Express way, Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor of Research, Iran 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

Iran University of Medical Sciences

Full name of responsible person

Dr Mohammad Reza Vafa

Position

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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