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

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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

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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