Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

The effect of vitamin D supplementation on inflammation and antioxidant markers and premenstrual syndrome(PMS) symptoms in vitamin D-deficient students

Protocol summary

Study aim
Determination of vitamin D supplementation on inflammatory markers (IL-10, IL-12), antioxidant (TAC), and physique and mood syndrome of students with premenstrual syndrome (PMS) and vitamin D deficiency

Design
Double-blind randomized clinical trial with parallel control group

Settings and conduct
The subjects from among 18-25 year-old female students with premenstrual syndrome and vitamin D deficiency in Isfahan University of medical sciences who have criteria for entering the study will be selected through multistage random cluster sampling

Participants/Inclusion and exclusion criteria
Aged 18-25 years, having normal BMI, single, serum vitamin D levels of 10-30 ng / ml, regular menstrual cycle with intervals of 21-35 days, lack of depression and anxiety, lack of diseases Acute and chronic, lack of iron deficiency anemia (anemia), lack of exercise on a regular basis, no use of combined tablets containing estrogens and progesterone , Lack of vitamin D supplementation in the past 3 months, the student does not start or finish the term in the semester

Intervention groups
During the four menstrual cycles, every two weeks, the intervention group receives an oral supplement of 50,000 units of vitamin D and the control group receiving a placebo that looks like vitamin D supplementation. People are asked to complete the PMS daily registration form during the last 2 additional cycles of supplemental supplementation. The amount of vitamin D intake will be collected through the Frequency Frequency Questionnaire. The levels of vitamin D, inflammatory markers and antioxidant in luteal phase and anthropometric information (weight, height, BMI and waist circumference) will be measured before and after intervention.

Main outcome variables
Levels of Interleukin 10 and 12 and total antioxidant capacity; Physical and psychological Symptoms of syndrome

General information

Reason for update

Acronym
PMS

IRCT registration information
IRCT registration number: **IRCT20180525039822N1**
Registration date: **2018-06-20, 1397/03/30**
Registration timing: **retrospective**

Last update: **2018-06-20, 1397/03/30**
Update count: **0**

Registration date
2018-06-20, 1397/03/30

Registrant information

Name
Hajar Heidari

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3324 3712

Email address
h.heidari72@ymail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-12-22, 1396/10/01

Expected recruitment end date

2018-01-21, 1396/11/01

Actual recruitment start date

2017-12-31, 1396/10/10

Actual recruitment end date

2018-02-02, 1396/11/13

Trial completion date

empty

Scientific title

The effect of vitamin D supplementation on inflammation and antioxidant markers and premenstrual syndrome(PMS) symptoms in vitamin D- deficient students

Public title

The effect of vitamin D supplementation on premenstrual syndrome(PMS)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 25-18 years BMI in normal range single Serum vitamin D level is 30- 10 ng / ml Having a regular menstrual cycle with intervals of 35 to 21 days Not doing regular exercise Students do not start or finish their studies in the semester

Exclusion criteria:

Acute and chronic diseases such as: cardiovascular, kidney, liver, diabetes, hypothyroidism, hyperthyroidism and asthma Iron deficiency anemia (Anemia) Depression and anxiety Consumption of combined pills containing estrogen and progesterone Take supplemental vitamin D in the last 3 months

Age

From **18 years** old to **25 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **44**

Actual sample size reached: **38**

Randomization (investigator's opinion)

Randomized

Randomization description

Multi-stage cluster randomization

Blinding (investigator's opinion)

Double blinded

Blinding description

Blindness will be that the supplementation of vitamin D and placebo will not be communicated to anyone by someone outside the research team and team members such as a researcher, clinical care provider, and supplementary participants

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jereb Street

City

Isfahan

Province

Isfehan

Postal code

8174673461

Approval date

2016-12-10, 1395/09/20

Ethics committee reference number

IR.MUI.REC.1395.3.734

Health conditions studied

1

Description of health condition studied

premenstrual syndrome

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Serum level of interleukin 10 based on ELISA method

Timepoint

At the beginning of the study and after 4 months of intervention

Method of measurement

Blood sampling and serum level determination using ELISA kit

2

Description

Serum level of interleukin 12 based on ELISA method

Timepoint

At the beginning of the study and after 4 months of intervention

Method of measurement

Blood sampling and serum level determination using ELISA kit

3

Description
Serum level of total antioxidant capacity based on ELISA method
Timepoint
At the beginning of the study and after 4 months of intervention
Method of measurement
Blood sampling and serum level determination using ELISA kit

4

Description
Score of physical symptoms and mood syndrome in premenstrual syndrome in the symptom registration questionnaire
Timepoint
At the beginning of the study and after 4 months of intervention
Method of measurement
Premenstrual Signs Indexing Questionnaire (DSM-IV)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: An oral supplement of 50,000 units of vitamin D from Tabriz's Zahrawi Company during 4 menstrual cycles every two weeks
Category
Treatment - Drugs

2

Description
Control group: Receiving a placebo that looks similar to vitamin D supplementation.Tabriz Zahravi company, it is administered every four weeks in 4 cycles
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
دانشگاه علوم پزشکی اصفهان
Full name of responsible person
Reza Amani
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan 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
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Hajar Heidari
Position
Masters student
Latest degree
Bachelor
Other areas of specialty/work
Nutrition

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
No more information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available