Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Aug 2026

The effect of vitamin D on severity of primary dysmenorrhea and amount of menstrual bleeding compared with placebo in students living in dormitories of Tehran University of Medical Sciences: Randomized, Double-blind, clinical trial

Protocol summary

Summary

Objectives: The aim of this study is to evaluate the effect of cholecalciferol on the severity of primary dysmenorrhea and amount of menstrual bleeding. Design: This study is a randomized, double-blind, clinical trial. Participants: Eighty single students aged 18 to 25 years with primary dysmenorrhea and 25(OH)D serum level < 30 ng/ml and normal serum calcium will be enrolled in this study. Setting and conduct: Eligible students from two dorms of tehran university of medical sciences will be evaluated for Pain score, severity of primary dysmenorrhea, amount of menstrual bleeding and use of NSAIDs (Non Steroidal Anti Inflammatory Drugs) within 3 cycles (Before intervention and the first and second cycle after intervention). At the end of study 25(OH)D and calcium serum level measured again. Intervention: 40 participants will be taken oral tablet of cholecalciferol (50000 IU of cholecalciferol 2 tablets every 8 hours) 5 days before the putative beginning of their next menstrual cycle, while another 40 participants receive placebo. Main outcome: Pain score, severity of primary dysmenorrhea and amount of menstrual bleeding will measure Before the intervention and the first and Second cycle after intervention. Comparison of results before and after intervention will be performed

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201305212324N9**
Registration date: **2014-01-18, 1392/10/28**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-01-18, 1392/10/28

Registrant information

Name
Maryam Keshavarz
Name of organization / entity
Iran University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

vice chancellor for research, Tehran University of Medical SciencesSixth floor ,Central office, Ghods St, Keshavarz Blvd, Tehran, Iran

Expected recruitment start date

2013-09-23, 1392/07/01

Expected recruitment end date

2013-12-22, 1392/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vitamin D on severity of primary dysmenorrhea and amount of menstrual bleeding compared with placebo in students living in dormitories of Tehran University of Medical Sciences: Randomized,

Double-blind, clinical trial

Public title
The effect of vitamin D on severity of primary dysmenorrhea and amount of menstrual bleeding
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Healthy, iranian and single female students aged 18 to 25 years؛ With normal menstrual cycles (cycles lasted 21 to 35 days, mensturation lasting 3 to 7 days)؛ Experienced at least 4 consecutive painful periods in the past 6 months with the pain starting a few hours before or just after the onset of bleeding؛ No history of underlying disease cause of secondary dysmenorrhea sush as: endometriosis and adenomyosis,etc؛ Don’t do any regular exercise؛ Lack of stressful experiences within 3 months prior؛ Don’t use of oral contraceptives and hormonal drugs within 3 months prior؛ Taking no medications including calcium and vitamin D within 6 months prior25 ؛(OH)D serum level ≤ 30 ng/ml and normal serum calcium؛ Having no unusual diets (vegetarian diets, special diet)؛ Don’t use of medicines that interact with vitamin D such as: hydantoin and barbiturates,etc؛ BMI ≤ 30؛ No smoking and alcohol consumption. Exclusion criteria: Lack of menstruation؛ Married during the study؛ Use of medications including calcium and vitamin D during the study؛ Use of oral contraceptives and hormonal drugs during the study ؛Use of non-pharmacological methods of pain relief ؛Intense psychological stress during the study؛ Start exercise during the study ؛Don’t use of supplement or interventions intended ؛Occurring gastrointestinal disorders after the consumption of supplement (Including vomiting 2 hours after the consumption of supplement ؛(Unwillingness to continue research.
Age
From **18 years** old to **25 years** old
Gender
Female

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size:
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

1

Registry name
no
Secondary trial Id
no
Registration date
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical commitment of Tehran University of Medical Sciences
Street address
Sixth floor ,Central office, Ghods St, Keshavarz Blvd- Tehran, Iran
City
Tehran
Postal code
Approval date
2013-09-24, 1392/07/02
Ethics committee reference number
1327/130/92

Health conditions studied

1

Description of health condition studied
primary dysmenorrhea
ICD-10 code
N94.4
ICD-10 code description
primary dysmenorrhea

Primary outcomes

1

Description
Pain score of primary dysmenorrhea
Timepoint
Before intervention, the first cycle after intervention, the Second cycle after intervention
Method of measurement
visual analog scale (VAS)

2

Description
Amount of menstrual bleeding
Timepoint
Before intervention, the first cycle after intervention, the Second cycle after intervention
Method of measurement
Pictorial blood loss assessment chart

3

Description
Severity of primary dysmenorrhea
Timepoint
Before intervention, the first cycle after intervention, the Second cycle after intervention
Method of measurement
Verbal multidimensional scoring system (VMS)

Secondary outcomes

1

Description
Use of NSAIDs
Timepoint
Before intervention, the first cycle after intervention, the Second cycle after intervention
Method of measurement
Record sheet of NSAID use

Intervention groups

1

Description
Contorol group will be received oral tablet of placebo, 2 tablets every 8 hours, 5 days before the putative beginning of their next menstrual cycle.
Category
Placebo

2

Description
Case group will be received oral tablet of cholecalciferol (50000 IU of cholecalciferol), 2 tablets every 8 hours, 5 days before the putative beginning of their next menstrual cycle.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Nastaran girls' dormitory of Tehran University of Medical Sciences
Full name of responsible person
Maryam Keshavarz
Street address
No 1, Jahans' alley, between Bahar and Shariati street, Talaghani street
City
Tehran

2

Recruitment center
Name of recruitment center
Amol girls' dormitory of Tehran University of Medical Sciences
Full name of responsible person
Maryam Keshavarz
Street address
No 138, Amol street, opposite the Pasargad hospital, Shariati street
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Tehran University of Medical Sciences
Full name of responsible person
Dr. Akbar Fotohi
Street address
Sixth floor ,Central office, Ghods St, Keshavarz Blvd- Tehran, Iran
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 for research, Tehran 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
School of Nursing and Midwifery, Tehran University of Medical Sciences
Full name of responsible person
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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