

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 4365 1813

###### Email address

keshavarz@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

vice chancellor for research, Tehran University of Medical Sciences Sixth 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, menstruation 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 such 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 prior! 25 :(OH)D serum level  $\leq$  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  $\leq$  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**

Control 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**

Elham Ghorbali

##### **Position**

Master of Midwifery

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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Master of Midwifery

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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*