

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### Effect of vitamin D on menstrual pain in women of childbearing age in comparison with placebo; double-blind randomized controlled clinical trial

#### Protocol summary

##### Summary

Primary menstrual pain is one of the most common menstrual disorders. It usually starts 6-12 months after first menstruation cycle. Fifty percentages of women of childbearing age suffer it and about 50% of people worldwide suffer from vitamin D deficiency too. Studies have shown that Vitamin D may reduce the symptoms of premenstrual syndrome, particularly pain. Based on our knowledge, 2 studies have examined the effect of vitamin D on menstrual cramps. The aim of this study was to investigate the effect of vitamin D supplementation on the menstrual pain in women of childbearing age. This study will be conducted as a randomized, double-blind clinical trial. Sixty women, 18 to 30 years old with Primary menstrual pain and 25 hydroxycholecalciferol  $\leq 30$ ng/ml are investigated in two intervention and control groups. Serum 25(OH) D3, magnesium, calcium, phosphorus, alkaline phosphates, and pain severity are measured in all participants. Intervention group is given cholecalciferol and the control group given placebo weekly for 2 months. The changes in laboratory tests, non-steroidal anti-inflammatory drugs consumption, and pain change severity will be compared 2 months after cholecalciferol administration in two groups. One month after discontinuation of the drug, the pain severity is measured and compared to the pain 2 months after treatment and baseline.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2012100110980N1**

Registration date: **2012-10-18, 1391/07/27**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2012-10-18, 1391/07/27

##### Registrant information

###### Name

Nooshin Shirzad

###### Name of organization / entity

Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 7771 9922

###### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

Tehran University of Medical Sciences

##### Expected recruitment start date

2013-02-19, 1391/12/01

##### 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

Effect of vitamin D on menstrual pain in women of childbearing age in comparison with placebo; double-blind randomized controlled clinical trial

##### Public title

The effect of vitamin D on primary menstrual pain

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Women aged 18-30 y; with normal menstrual cycles (cycles lasted 21 to 35, with menstrual lasting 3 to 7 days); at least 4 consecutive painful periods in the past 6 months with a diagnosis of primary dysmenorrhea; Serum 25-hydroxyvitamin D level  $\leq$  30 ng/dl. Exclusion criteria: Secondary menstrual pain diagnosed by ultrasound examination; Previous and current use of intrauterine contraceptive devices within the 6 months prior; Previous and current use of drugs including calcium or vitamin D within the 6 months prior; Recent use of oral contraception drugs during the past 2 months; Smoking; BMI  $\geq$  30; history of kidney stones; granulomatous disease; hyperparathyroidism and any malignant disease.

**Age**

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

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

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

Double blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Tehran University of Medical Sciences, Deputy of Research

**Street address**

Qods St, Keshavarz Blvd

**City**

Tehran

**Postal code****Approval date**

2013-01-21, 1391/11/02

**Ethics committee reference number**

91-04-39-19158-77016

**Health conditions studied****1****Description of health condition studied**

primary dysmenorrhoea

**ICD-10 code**

N94.4

**ICD-10 code description**

primary dysmenorrhoea

**Primary outcomes****1****Description**

Menstrual pain severity

**Timepoint**

before treatment, 2 months after the treatment, 1 month after finishing intervention

**Method of measurement**

Visual pain scale

**Secondary outcomes**

empty

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

intervention group: cholecalciferol 50,000 IU oral tablets, once a week for 8 weeks.

**Category**

Treatment - Drugs

**2****Description**

control group: placebo, oral tablet, once a week for 8 weeks.

**Category**

Placebo

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Arash women's hospital

**Full name of responsible person**

Shahrzad Jafari-Adli

**Street address**

Arash Women 's Hospital, Rashid Ave., Resalat Highway, Tehranpars

**City**

Tehran

**Sponsors / Funding sources**

## 1

### Sponsor

**Name of organization / entity**

Tehran University of Medical Sciences, Deputy of Research

**Full name of responsible person**

Dr Akbar Fotouhi

**Street address**

Ghods St., Keshavarz Blvd. Vali-e-Asr Ave.

**City**

Tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Tehran University of Medical Sciences, Deputy of Research

**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**

Tehran University of Medical Sciences (TUMS)

**Full name of responsible person**

Shahrzad Jafari-Adli

**Position**

general practitioner

**Other areas of specialty/work****Street address**

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### Person responsible for scientific inquiries

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### Person responsible for updating data

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**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*