Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 ≤30ngm/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 cholecalsiferol administration in tow 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

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Name of organization / entity
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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 ≤ 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 ≥ 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

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

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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

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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