

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

Improvement of Primary Dysmenorrhea Caused by a Single Oral Dose of Vitamin D: Results of a Randomized, Double-blind, Placebo-Controlled Study

Protocol summary

Summary

The aim of this prospective intervention study was to evaluate the effect of a single - loading oral dose of Cholecalciferol(300000IUs) ON Primary Dysmenorrhea. Fifty four women aged 18 to 35 years with inclusions and exclusions criterias , attending the outpatient clinics of the Department of Internal Medicine of the University of Kermanshah , for primary dysmenorrhea were enrolled. Women were randomized in to 2 groups: 27 women received a single oral dose of Cholecalciferol(300000IUs) 5 days before the putative beginning of their next menstrual cycle,while another 20 women received Placebo. The primary outcome was the intensity of menstrual pain as measured by a visual analog scale. The secondary outcome was use of NSAIDs during the 3-month duration of the study. They showed a 25(OH)D serum level. The study was performed between march 2012 and May 2013.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013022312582N1**
Registration date: **2013-08-18, 1392/05/27**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-08-18, 1392/05/27

Registrant information

Name

Mina Ataee

Name of organization / entity

Medical University of Kermanshah

Country

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Phone

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Email address

ataee.mina@yahoo.com

Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences

Expected recruitment start date

2012-11-21, 1391/09/01

Expected recruitment end date

2013-05-21, 1392/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Improvement of Primary Dysmenorrhea Caused by a Single Oral Dose of Vitamin D: Results of a Randomized, Double-blind, Placebo-Controlled Study

Public title

Effect of Single Oral Dose of Vitamin D in Primary Dysmenorrhea

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criterias :Their menstrual cycles lasted 21 to 35 days; With menstruation lasting 3 to 7 days; They experienced at least 4 consecutive painful periods in the past 6 months with the pain starting one day before or on the day of onset of bleeding; They showed a 25(OH)D serum level; Patients had to be in good health and taking

no medications including calcium, vitamin D, and oral contraceptives; Sonography of ovary and uterine is normal in the past 6 months. Exclusion Criteria: Had no Their menstrual cycles lasted 21 to 35 days; had no With menstruation lasting 3 to 7 days; They no experienced at least 4 consecutive painful periods in the past 6 months with the pain starting one day before or on the day of onset of bleeding; Patients had no be in good health and taking medications including calcium, vitamin D, and oral contraceptives; Sonography of ovary and uterine is abnormal in the past 6 months.

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: **54**

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**

Kermanshah University of Medical Sciences

Street address

Building No 2, Shahid Beheshti Blv, Medical University of Kermanshah

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kermanshah

Postal code**Approval date**

2012-11-21, 1391/09/01

Ethics committee reference number

1/420/7/پ

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

primary dysmenorrhea

ICD-10 code

N94.4

ICD-10 code description

Primary dysmenorrhoea

2**Description of health condition studied**

Vitamin D deficiency

ICD-10 code

E55.9

ICD-10 code description

Vitamin D deficiency, unspecified

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

The intensity of menstrual pain

Timepoint

before, 1 and 3 months after intervention

Method of measurement

visual analogue scale(VAS)

Secondary outcomes**1****Description**

Use of NSAIDs

Timepoint

before, 1 and 3 months after intervention

Method of measurement

asking from subjects

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

The intervention group received a single oral dose of cholecalciferol (300 000 IUs) 5 days before the putative beginning of their next menstrual cycle and NSAIDs.

Category

Treatment - Drugs

2**Description**

The Placebo group received a placebo drug cholecalciferol 5 days before the putative beginning of their next menstrual cycle and NSAIDs.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center**

Name of recruitment center

Kermanshah University of Medical Sciences

Full name of responsible person

Mina Ataee

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**Basic Sciences, Kermanshah University of Medical
Sciences**Full name of responsible person**

Ms Faraj Roshanpoor

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

Yes

Title of funding sourceBasic Sciences, Kermanshah 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**Kermanshah University of Medical Sciences and
Research**Full name of responsible person**

Mina Ataee

Position

Resident of Gynecology and Obstetrics

Other areas of specialty/work**Street address**Building No 2, Shahid Beheshty Blv, Medical
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Postal code**Person responsible for scientific
inquiries****Contact****Name of organization / entity**

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Person responsible for updating data**Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Mina Ataee

Position

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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