Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 thise prospective intervention study wase to evaluate the effect of a single - loading oral dose of Cholecalciferol(300000IUs) ON Primary Dysmenorrhea. Fifty fore women aged 18 to 35 years with iclutions and exclutions criterias , attending the outpatient clinics of the Department of Internal Medicine of the University of Kermanshah , for pimary 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 Uneversity of Kermanshah

Country

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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 Dysmenorhea

Purpose

Treatment

Inclusion/Exclusion criteria

Inclution 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;Sonografy of ovary and utrian is normal in the past 6 months. Exclutios 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; Sonografy of ovary and utrian 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 Beheshty Blv, Medical Uneversity of Kermanshah

City
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 dysmenorhea

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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Building No 2, Shahid Beheshty Blv, Medical Uneversity of Kermanshah
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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
Street address
Building No 2, Shahid Beheshty Blv, Medical Uneversity of Kermanshah
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Basic 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
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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