

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 2026

The effect of vitamin D on primary dysmenorrhea

Protocol summary

Summary

The aim of this study was to determine the effect of vitamin D supplements on the severity of primary dysmenorrhea in students living in dormitories of Shahid Beheshti University of Medical Sciences. This randomized double-blind controlled clinical trial is conducted on 200 students with inclusion and exclusion criteria. The inclusion criteria the Iranian population are aged between 18-30 years, history of primary dysmenorrhea in 4 recent cycles or 6 months, menstrual cycle 3-7 days, absence of abnormal uterine bleeding, regular menstrual cycles of 22-35 days according to their statements, lack of Pregnancy, having a reading and writing skills, a willingness to participate in the study. Exclusion criteria for secondary dysmenorrhea, unwillingness to continue treatment or take medication, incidence of certain conditions, such as pregnancy, sensitivity, specific and chronic diseases, and forced to intake drug during the study, stressful events such as close families death and surgical procedures. Eligible patients are randomly assigned in to two groups of intervention (capsule of 50,000 units per week or 20,000 units per day vitamin D) and the control group (placebo). The units of the study consume vitamin D capsules two weeks before the menstrual period. And they can use a variety of nonsteroidal anti-inflammatory drugs during treatment, but they should report their type and dose. The study of dysmenorrhea severity by using Multidimensional Scale (Andrich & Millson) Scale before and after treatment in both groups for 4 cycles or 16 weeks, and then the results will analyze by appropriate statistical tests

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201707223860N32**

Registration date: **2017-09-16, 1396/06/25**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-09-16, 1396/06/25

Registrant information

Name

Gity Ozgoli

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8820 2512

Email address

gozgoli@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences and personal

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2018-08-21, 1397/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vitamin D on primary dysmenorrhea

Public title

The effect of vitamin D on women with menstrual pain

Purpose

Treatment

Inclusion/Exclusion criteria

sex:female: age:18-30 years old : experienced primary

dysmenorrhea :The period of: bleeding between 3-7 days:lack of AUB between bleeding period:regular cycles with 22-32 days:Having reading and writing skills:The desire to participate in the study:BMI between 18.5-29:Lack of Pregnancy or Intent in the next three months:No use of contraceptive methods and IUD

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: **200**

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

school of nursing and midwifery,shahid beheshti university of medical science

Street address

valliasr street, Niayeesh crossover, school of nursing and midwifery.shahid beheshti university of medical science

City

Tehran

Postal code

Approval date

2017-07-01, 1396/04/10

Ethics committee reference number

IR.SBMU.PHNM.1396.772

Health conditions studied

1

Description of health condition studied

primary dysmenorrhea

ICD-10 code

N94

ICD-10 code description

Pain and other conditions associated with female genital organs and menstrual cycle

Primary outcomes

1

Description

Score of early menstrual pain

Timepoint

Before the intervention, the first cycle after the intervention, the second cycle after the intervention

Method of measurement

Visual Scale of Pain

2

Description

Menstrual bleeding

Timepoint

Before the intervention, the first cycle after the intervention, the second cycle after the intervention

Method of measurement

Picture of blood loss

3

Description

Severity of dysmenorrhea

Timepoint

Before the intervention, the first cycle after the intervention, the second cycle after the intervention

Method of measurement

Verbal Multi-dimensional Scoring System (Andrich & Wilson)

Secondary outcomes

1

Description

sedation Consumption

Timepoint

Cycle before intervention, first cycle after intervention, second cycle after intervention

Method of measurement

Cycle before intervention, first cycle after intervention, second cycle after intervention

Intervention groups

1

Description

Interventional group with vitaminD supplements

Category

Treatment - Drugs

2

Description

control group

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Dormitories of Shahid Beheshti University of Medical Sciences

Full name of responsible person

Fatemeh Sadat Rahnemaie

Street address

Vali-Asr Avenue, Cross of Vali-Asr and Neiaiesh Highway, Opposite to Rajae Heart Hospital, Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Dept. of Research, School of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dolatian M

Street address

Valiasr Avenue, Niayesh cross over facing Shahid Rajae Heart Hospital

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Dept. of Research, School of Nursing and Midwifery, Shahid Beheshti 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, shahid beheshti university of medical science

Full name of responsible person

Fatemeh Sadat Rahnemaie

Position

MsC of midwifery

Other areas of specialty/work

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Department of Reproductive Health and Midwifery, School of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences (1th floor), Vali-Asr Avenue, Cross of Vali-Asr and Neiaiesh Highway, Opposite to Rajae Heart Hospital, Tehran, Iran

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Associated Professor of Reproductive health, Department of Midwifery and Reproductive Health, Shahid

Full name of responsible person

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Position

PhD of reproductive health

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