Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
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Iran (Islamic Republic of)
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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 Rajaee Heart Hospital, Tehran, Iran
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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 Rajaee Heart Hospital
City
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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
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
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Person responsible for scientific inquiries

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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