Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Investigating the effect of low dose vitamin D on intensity of dysmenorrhea

Protocol summary

Study aim
Determining the intensity of dysmenorrhea pain in the two intervention and control groups before, immediately, 1, 3 and 6 months after the intervention

Design
Double Blind Randomized Placebo Controlled Trial

Settings and conduct
Participants will be recruited via convenience sampling by referring to different faculties of Qazvin University of Medical Sciences. eligible people with the desire to participate in the study are registered. Then random allocation in two groups will be done by balanced block randomization method with block size of 4. Participants, researchers, outcome assessors, and data analysts will be blinded to the study groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1. Moderate to severe primary dysmenorrhea (score higher than 4 based on visual pain scale) 2. Single 3. At reproductive ages (18 to 35 years) 4. Student of Qarvin University of Medical Sciences 5. Willingness to participate in the study Exclusion criteria: 1. Existence of secondary dysmenorrhea and its predisposing factors such as history of endometriosis, adenomyosis, subacute endometritis, pelvic inflammatory disease, copper intrauterine devices, ovarian cysts, congenital pelvic malformations and cervical stenosis based on individual statement. 2. History of known mental illness based on individual statement 3. Drug addiction based on a person's statement 4. Probability of graduation during the follow-up period 5. Use vitamin D or calcium supplements 6. Concomitant use of corticosteroids, anticonvulsants, anti-tuberculosis, anti-hypertensive drugs that interfere with the absorption of vitamin D

Intervention groups
Intervention group with vitamin capsule 1000 units / control group with placebo capsule

Main outcome variables
Intensity of dysmenorrhea pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180218038789N3**
Registration date: **2020-09-15, 1399/06/25**
Registration timing: **prospective**

Last update: **2020-09-15, 1399/06/25**
Update count: **0**

Registration date
2020-09-15, 1399/06/25

Registrant information

Name
Zainab Alimoradi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 28 3333 6003

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z.alimoradi@qums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-10-22, 1399/08/01

Expected recruitment end date
2021-05-20, 1400/02/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Investigating the effect of low dose vitamin D on intensity of dysmenorrhea

Public title

Effect of vitamin D on intensity of dysmenorrhea

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Moderate to severe primary dysmenorrhea (score above 4 based on visual pain scale) Being Single Being at reproductive ages (18 to 35 years) Student of Qazvin University of Medical Sciences Willingness to participate in the study

Exclusion criteria:

Presence of secondary dysmenorrhea and its underlying factors such as history of endometriosis, adenomyosis, subacute endometritis, pelvic inflammatory disease, copper intrauterine devices, ovarian cysts, congenital pelvic malformations and cervical stenosis based on individual statement Concurrent use of corticosteroids, anticonvulsants, anti-TB, anti-hypertension, which interfere with the absorption of vitamin D. Use vitamin D or calcium supplements Probability of graduation during the follow-up period History of known mental illness based on individual statement Drug addiction based on self disclosure

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **92**

Randomization (investigator's opinion)

Randomized

Randomization description

Individuals will be assigned to intervention groups and placebo by block randomization method using 4 blocks. Given that the two groups will be studied, blocks with size of 4 are used and each letter is assigned to a group (A: intervention group, B: comparison group). All possible modes are written and numbered for a block of 4, such as: 1.AABB 2.ABAB 3.BBAA 4.BABA 5.ABBA 6.BAAB 7 .--- Then, in a simple random method (using a table of random numbers), a number of numbers are selected from the block numbers and by writing the contents of the blocks related to those numbers (until the specified sample size is obtained), The random assignment sequence is specified. For example, if the numbers obtained are 3, 2, 2, 1, etc., respectively, the assignment sequence will be as follows: AABB ABAB ABAB BBAAThe type of intervention is then written based on the allocation sequence and placed in envelopes in a matte package. The envelopes are coded in order. In this case, for the person who receives the intervention code 1, a questionnaire with the same code is completed.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Blinding of medicine and placebo capsules will be done by the pharmaceutical company. The drug and placebo will be similar in shape, color and smell and will be provided to the researcher with the code a, b. The participant, researcher, outcome assessor, and data analyst will be unaware of the codes until the end of the analysis. At the end of the analysis, codes specific to each group will be taken from the pharmaceutical company.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Qazvin University of Medical Sciences

Street address

Bahonar Bulevard, Qazvin University of Medical Sciences

City

Qazvin

Province

Qazvin

Postal code

3419759811

Approval date

2020-05-17, 1399/02/28

Ethics committee reference number

IR.QUMS.REC.1399.033

Health conditions studied

1

Description of health condition studied

Primary dysmenorrhea

ICD-10 code

N94.4

ICD-10 code description

Primary dysmenorrhea

Primary outcomes

1

Description
Intensity of dysmenorrhea pain
Timepoint
Before, Immediately, 1, 3, 6 months after intervention
Method of measurement
Visual analogue scale

Secondary outcomes

1

Description
Duration of dysmenorrhea pain
Timepoint
Before, immediately, 1, 3 and 6 months after the intervention
Method of measurement
Individual report of pain duration by day

2

Description
Need to use pain killer
Timepoint
Before, immediately, 1, 3 and 6 months after the intervention
Method of measurement
Individual report of need to use pain killer

3

Description
Menstrual distress
Timepoint
Before, immediately, 1, 3 and 6 months after the intervention
Method of measurement
Moos questionnaire of menstrual distress

Intervention groups

1

Description
Intervention group: Capsule of Vitamin D 1000 IU// These capsules will be provided by Nanohiat Pharmaceutical Company. Vitamin D capsules with a dose of 1000 units are prepared for daily use. The intervention plan is to prescribe one capsule daily for two consecutive months. Each eligible participant is asked to start taking the capsules when menstrual bleeding begins and to take one capsule daily for two months after the initial assessments.
Category
Prevention

2

Description
Control group: Placebo capsule// These capsules will be provided by the same company in exactly the same way as the capsules containing the drug in terms of size, shape and color. The intervention plan is to prescribe one capsule daily for two consecutive months. Each eligible participant, after initial assessments, is asked to start taking the capsules when menstrual bleeding begins and to take one capsule daily for two months.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Faculties of Qazvin University ogf a
Full name of responsible person
Zainab Alimoradi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Dr. Mohammad Mahdi Emam Jomeh
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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
Qazvin University of Medical Sciences
Proportion provided by this source

100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Qazvin University of Medical Sciences

Full name of responsible person
Zainab Alimoradi

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Reproductive Health

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Participants' personal data is shared in an unidentifiable manner along with the publication of the final article

When the data will become available and for how long
After the completion of study

To whom data/document is available
there is no limitation

Under which criteria data/document could be used
there is no limitation

From where data/document is obtainable
Email to corresponding author

What processes are involved for a request to access data/document
Specify the purpose of the need to access the data

Comments