Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Effect of combined calcium-vitamin D and only calcium on pain severity and menstrual bleeding in students with primary dysmenorrhea: a randomized placebo-controlled trial

Protocol summary

Summary

The objective of this triple-blind trial is to determine effect of combined calcium-vitamin D and only calcium on pain and bleeding in students with primary dysmenorrhea. Ninety students with moderate to severe dysmenorrhea residing in Tabriz dormitories will be allocated into three groups with allocation ratio 1:1:1 and block sizes of 3, 6 and 9. The participants will take combined (1000 mg calcium and 5000 IU vitamin D), only calcium (1000 mg), or placebo tablets daily from approximately 14 days before starting menstrual flow until relieving dysmenorrhea pain in the next cycle (about 18 tablets each cycle) for 3 consecutive cycles. The tablets are identical in terms of size, color, etc. To maintain blinding, a person not involved in the recruitment and data collection will determine allocation sequence and will put the tablets in opaque sealed consecutively numbered envelopes. Gelofen tablets will be given to all participants to use to relieve menstrual pain, if needed. Primary outcomes are pain severity and bleeding amount which will be assessed by visual analogue scale and Hygam chart, respectively. Secondary outcomes are quality of life (assessed by SF36), the number of taken analgesics (Gelofen), satisfaction with treatment and adverse events. Outcomes will be assessed during three months under intervention and one month after intervention. ANCOVA and repeated measurement tests will be used to compare the groups in terms of pain score, amount of bleeding, quality of life, and the number of taken analgesics. Satisfaction with treatment will be compared using Mann-Whitney test.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201402043706N21**
Registration date: **2014-02-22, 1392/12/03**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2014-02-22, 1392/12/03

Registrant information

Name

Sakineh Mohammad-Alizadeh-Charandabi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 41 3477 2699

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2014-02-26, 1392/12/07

Expected recruitment end date

2014-03-20, 1392/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of combined calcium-vitamin D and only calcium on pain severity and menstrual bleeding in students with

primary dysmenorrhea: a randomized placebo-controlled trial

Public title
Effect of combined calcium-vitamin D and only calcium on pain severity and menstrual bleeding in students with primary dysmenorrhea

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: • painful and regular (35-21 days cycles) menstrual cycles during previous 3 months with maximum pain severity score of 5.0 to 9.1 assessed by VAS (0-10). • Having pain with features of primary dysmenorrhea (constant lower abdominal pain, radiating to the back or the anterior or medial thigh, starting several hours before or just after the menstrual flow). • No Known chronic disease (including epilepsy, gastrointestinal, cardio-vascular or renal diseases). • Being single. Exclusion criteria: • No access to a phone line (for follow-up). • Occurrence of any type of genital diseases or abdominal or pelvic surgery in the last 6 months. • Experiencing any severe psychological stress, such as parental divorce, death of first degree relatives, etc. in the last 6 months. • Experiencing heavy vaginal bleeding (using a pad every hour for at least 6 hours) or continuous spotting between menstrual periods is in the last 6 months. • Having allergy to non-steroidal anti-inflammatory drugs. • Frequent and regular intake of supplements (including calcium, vitamin D, zinc, iron) in the last 3 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: **90**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
In this study, participants will be recommended to take no pharmacological or non-pharmacological analgesic for dysmenorrhea pain relief during study period, except the Gelofen tablets (which will be given them by the investigators) and record number of the taken tablets. Stratified allocation based on amount of calcium and vitamin D intake (assessed using a food frequency questionnaire) will be used to have equal number of subjects with calcium and vitamin D deficiency in the three groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee in Tabriz University of Medical Sciences

Street address
3rd floor, Centeral building No 2, Tabriz University of Medical Sciences, Golgasht st.

City
Tabriz

Postal code

Approval date
2013-12-02, 1392/09/11

Ethics committee reference number
92145

Health conditions studied

1

Description of health condition studied
Primary dysmenorrhea

ICD-10 code
N94.4

ICD-10 code description
Primary dysmenorrhoea

Primary outcomes

1

Description
Severity of Menstrual pain

Timepoint
1) one cycle before treatment 2) the first, second and third cycles under treatment 3) first cycle after treatment

Method of measurement
VAS

2

Description
Amount of menstrual bleeding

Timepoint
1) one cycle before treatment 2) first, second and third cycles under treatment 3) first cycle after treatment

Method of measurement
Hygam chart

Secondary outcomes

1

Description
Health-related Quality of life

Timepoint
1) One cycle before treatment 2) the third cycle of the treament
Method of measurement
SF36 Health-related quality of life questionnaire

2

Description
Number of consumed analgesics tablets
Timepoint
1) one cycle before treatment 2) 1,2,3 cycle during treatment 3) 1 cycle after treatment
Method of measurement
Daily recording in questionnaire

3

Description
Satisfaction with treatment
Timepoint
1) one cycle before treatment 2) three cycle under treatment 3) one cycle after treatment
Method of measurement
Self-report

4

Description
Side events
Timepoint
1) one cycle before treatment 2) three cycle during treatment 3) one cycle after treatment
Method of measurement
Self-report

Intervention groups

1

Description
Intervention group I: Subjects will take one combined tablet containing calcium (1000 mg) and vitamin D (5000 IU) daily from about 2 weeks before starting bleeding flow until dysmenorrhea pain relief in the next cycle (about 18 tablets a cycle) for three consecutive cycles
Category
Treatment - Drugs

2

Description
Intervention group II: Subjects will take one tablet containing 1000 mg calcium daily from about 2 weeks before starting bleeding flow until dysmenorrhea pain relief in the next cycle (about 18 tablets a cycle) for three consecutive cycles
Category
Treatment - Drugs

3

Description
Intervention group III: Subjects will take a placebo tablet daily from about 2 weeks before starting bleeding flow until dysmenorrhea pain relief in the next cycle (about 18 tablets a cycle) for three consecutive cycles
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Student dormitories in Tabriz
Full name of responsible person
Somayeh Zarei - MSc student in midwifery
Street address
Kousar dormitory, South Shariatie, Tabriz
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research deputy of Tabriz university of medical sciences
Full name of responsible person
Dr. Mohammad Reza Rashidi
Street address
Research Deputy, 3rd floor,Centeral building No 2 , Tabriz University of medical Sciences, Golgasht st., Tabriz
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research deputy of Tabriz 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
Midwifery Department, Faculty of Nursing & Midwifery, Tabriz University of Medical Sciences

Full name of responsible person
Somaye Zarei
Position
MSc student in midwifery
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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