

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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)

Phone

+98 41 3477 2699

Email address

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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 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, Central 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 treatment

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

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Research Deputy, 3rd floor, Central 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

Other areas of specialty/work**Street address**

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Full name of responsible person

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Position

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Full name of responsible person

Sakineh Mohammad-Alizadeh-Charandabi

Position

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Web page address**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