Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effects of calcium and vitamin B1 on the severity of menstrual distress in 18-26 year old girls residing in dormitories

Protocol summary

Study aim

To compare of the effect of calcium and vitamin B1 on the severity of menstrual distress

Design

A clinical trial with a control group and 2 experimental groups, with parallel groups, triple-blind, randomized, phase 3 on 123 patients, where Excel software was used for randomization.

Settings and conduct

In this triple-blind study, students living in dormitories of Torbat Heydariyeh University of Medical Sciences, in Iran assigned to 3 groups. Each person participated in the study for 4 cycles. The first cycle was to record the severity of menstrual pain and distress, 2 cycles of taking the drug or placebo, and the last cycle was to record the outcome.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Being Iranian; Being single; Being at most 28 years old; Having symptoms of menstrual distress for at least 3 cycles in the last 6 months; Having mild to moderate dysmenorrhea by Visual Analog Scale (2≤VAS ≤8). Exclusion criteria: having symptoms of secondary dysmenorrhea; having a history of any chronic medical disease; use psychoactive drugs; having experience of using oral contraceptive pills in the previous 6 months; following a special diet.

Intervention groups

Intervention Group 1: Vitamin B1 Consumers: In this group, the research units will use a capsule containing 100 mg of thiamine hydrochloride, lactose, and microcrystalline cellulose daily for two months. Intervention Group 2: Calcium Consumers: In this group, the research units will use a capsule containing 600 mg of calcium carbonate daily for two months, as well as some lactose and microcrystalline cellulose as excipients. Control Group: In this group, the research units will use a placebo capsule containing some lactose and microcrystalline cellulose daily for two months.

Main outcome variables

Pain score, menstrual distress severity score, side effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250226064862N1**
Registration date: **2025-07-01, 1404/04/10**
Registration timing: **retrospective**

Last update: **2025-07-01, 1404/04/10**
Update count: **0**

Registration date

2025-07-01, 1404/04/10

Registrant information

Name

Maryam Kabirian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3604 4338

Email address

kabirianm1@thums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-08-22, 1403/06/01

Expected recruitment end date

2025-01-20, 1403/11/01

Actual recruitment start date

2024-09-05, 1403/06/15

Actual recruitment end date

2025-01-24, 1403/11/05

Trial completion date

2025-01-24, 1403/11/05

Scientific title
Comparison of the effects of calcium and vitamin B1 on the severity of menstrual distress in 18-26 year old girls residing in dormitories

Public title
Effect of calcium and vitamin B1 on the severity of menstrual distress

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Being Iranian Being single Being at most 28 years old Having symptoms of menstrual distress for at least 3 cycles in the last 6 months Having mild to moderate dysmenorrhea by Visual Analog Scale (2≤VAS ≤8) Having regular menstrual cycle Having a normal body mass index .

Exclusion criteria:
Having symptoms of secondary dysmenorrhea Having a history of any chronic medical disease Use psychoactive drugs Having experience of using oral contraceptive pills in the previous 6 months Following a special diet Using of tobacco or alcoholic beverages Being a professional athlete

Age
From **18 years** old to **26 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **150**
Actual sample size reached: **123**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, the research units were individually and randomly assigned to three groups: calcium consumers, vitamin B1 consumers, and control. After preparing a list of research units with inclusion criteria, Excel software was used for randomization, and the randomization was completely hidden and based on the number of research units. For this purpose, all research units that met the inclusion criteria were assigned a number, which, based on the expected required sample size, created a total numerical range between 1 and 150. Then, the RANDARRY function in Excel was used to select random data without repetition in the three study groups.

Blinding (investigator's opinion)
Triple blinded

Blinding description
In order to blind the study, drugs were prepared as coded tablets. The second researcher distributed the supplements without knowing the code of the tablets (60 tablets to each group for consumption in a period of 2 months) and the participants were unaware of the type of tablets consumed during the study. Also, data analysis was done blindly.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Torbat Heydariyeh University of Medical Sciences

Street address
University Campus, Mehr boulevard, Valiasr street

City
Torbat Heydariyeh

Province
Razavi Khorasan

Postal code
9516160061

Approval date
2018-02-20, 1396/12/01

Ethics committee reference number
IR.THUMS.REC.1396.45

Health conditions studied

1

Description of health condition studied
Dysmenorrhea

ICD-10 code
N94.6

ICD-10 code description
Dysmenorrhea, unspecified

Primary outcomes

1

Description
Severity of pain

Timepoint
One cycle before the intervention and one cycle after the intervention

Method of measurement
Visual Analog Scale

2

Description

Menstrual distress

Timepoint

One cycle before the intervention and one cycle after the intervention

Method of measurement

Moos Menstrual Distress Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Research units in the control group will receive one placebo capsule containing lactose and microcrystalline cellulose daily for two months without the active ingredient in terms of calcium and vitamin B1. The capsules in the three groups were identical in color, shape, and size and were produced by the Industrial Pharmaceutical Laboratories of the Faculty of Pharmacy, Mashhad University of Medical Sciences.

Category

Placebo

2

Description

Intervention Group 1: Research units in this group will receive one capsule containing 100 mg of thiamine hydrochloride, lactose, and microcrystalline cellulose daily for two months.

Category

Treatment - Drugs

3

Description

Intervention Group 2: Research units in this group will receive one capsule containing 600 mg of calcium carbonate, lactose, and microcrystalline cellulose daily for two months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dormitories of Torbat Heydariyeh University of Medical Sciences

Full name of responsible person

Mohadese Adeli

Street address

University Campus, Mehr boulevard, Valiasr street

City

Torbat Heydariyeh

Province

Razavi Khorasan

Postal code

9516160061

Phone

+98 51 5242 1000

Email

Kabirianm1@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Torbate-Heidaria University of Medical Sciences

Full name of responsible person

Dr Mohammad Ahmadi

Street address

University Campus, Mehr boulevard, Valiasr street

City

Torbat Heydariyeh

Province

Razavi Khorasan

Postal code

9516160061

Phone

+98 51 5242 1000

Email

Mostafaahmadi24@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Torbate-Heidaria 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

Torbate-Heidaria University of Medical Sciences

Full name of responsible person

Maryam Kabirian

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

Valiasr St., Mehr Blvd., Torbat Heydariyeh University of Medical Sciences Campus

City
Torbat Heydariyeh

Province
Razavi Khorasan

Postal code
9516160061

Phone
+98 51 5242 1000

Email
Kabirianm1@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Torbate-Heidaria University of Medical Sciences

Full name of responsible person
Maryam Kabirian

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Reproductive Health

Street address
University Campus, Mehr boulevard, Valiasr street

City
Torbat Heydariyeh

Province
Razavi Khorasan

Postal code
9516160061

Phone
+98 51 5242 1000

Email
Kabirianm1@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Torbate-Heidaria University of Medical Sciences

Full name of responsible person
Maryam Kabirian

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

Street address
No. 112, Jalal Al Ahmad 27

City
Mashhad

Province
Razavi Khorasan

Postal code
9188777557

Phone
+98 51 3604 4338

Fax

Email
kabirianm1@thums.ac.ir

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
Yes - There is a plan to make this available

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
All data is potentially shareable after de-identifying individuals.

When the data will become available and for how long
Access period starts 6 months after results are published.

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
The data will be de-identified and usable for the purpose of developing knowledge.

From where data/document is obtainable
Documents can be received via email at Kabirianm1@gmail.com and Maryam Kabirian will be responsible.

What processes are involved for a request to access data/document
The request will be sent via email and will be available after a period of 1 week for coordination with other members of the research team and preparation of documentation.

Comments