

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

The effectiveness of calcium with magnesium and only calcium on the pain severity and resting time with primary dysmenorrhea: a triple-blind randomized controlled trial

Protocol summary

Summary

The aim of this randomized controlled trial is to determine effectiveness of only calcium and calcium with magnesium on the pain severity and resting length of students with primary dysmenorrhoea. 80 female eligible students with medium to severe primary dysmenorrhoea ($VAS \geq 5$) will be recruited at dormitories of Aras branch of Tabriz University of Medical Sciences, after getting written informed consent. The participants will fill in forms reporting severity of pain and other menstrual symptoms, as well as amount of menstrual bleeding on each day of menstrual cycle during 2 following months and the end of the 2 months give them to the researcher. 60 of the recruited people, who have good cooperation in reporting the symptoms, will be randomized using blocks sized 6 and 9 into 3 groups. One group will get capsule of calcium, the second combination of calcium and magnesium and the third one placebo which are identical in terms of size, colour, ... They will be instructed to use them from 15th day of menstruation cycle till end of following menstrual pain and fill in the similar questionnaire as the 2 previous months. They will be given Mefenamic acid capsules to use during the 4 months study cycles, if needed, but they have to report number of the capsules used. The groups will be compared in terms of mean pain score, symptom severity score, resting time, number of Mefenamic acid used, amount of blood menstruation using Covariance test.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202013706N10**

Registration date: **2012-05-13, 1391/02/24**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-05-13, 1391/02/24

Registrant information

Name

Sakineh Mohammad-Alizadeh-Charandabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3477 2699

Email address

alizades@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2012-05-14, 1391/02/25

Expected recruitment end date

2012-06-14, 1391/03/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of calcium with magnesium and only calcium on the pain severity and resting time with primary dysmenorrhoea: a triple-blind randomized controlled trial

Public title

The effectiveness of calcium with magnesium and only

calcium on the pain severity and resting length with primary dysmenorrhea

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Single students aged 18-34 years residing in Aras dormitory, having primary dysmenorrhea, regular and painful menstruation in previous 1 year with pain score equal or more than 5 according to visual analogue scale (medium to severe dysmenorrhea); consent to participate the study

Exclusion criteria: Known serious diseases like epilepsy, severe digestive disorders, cardiovascular or renal diseases, pelvic inflammatory diseases; consumption of oral contraceptive pills in previous 6 months or desire to take them during study; allergy to NSAIDs.

Age

From **18 years** old to **34 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Deputy, Tabriz University of Medical Sciences

Street address

Golgasht

City

Tabriz

Postal code

Approval date

2012-01-16, 1390/10/26

Ethics committee reference number

9081

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

mean severity of menstrual pain

Timepoint

for 2 months after intervention, 1 day before starting menstruation to 3 days after it, measured once every 6 hours

Method of measurement

Visual Analogue Scale

2

Description

resting length due to dysmenorhea

Timepoint

for 2 months after intervention

Method of measurement

daily recording of resting length by the participants on a form

Secondary outcomes

1

Description

Symptom Severity during Menstruation

Timepoint

during 2 months after intervention

Method of measurement

Symptom Severity Scale

2

Description

Need to take additional pain relief drug for dysmenorrhea

Timepoint

for two months after starting intervention

Method of measurement

No of Mephenamic Capules used

3

Description

volume of menstrual bleeding

Timepoint

for two months after starting intervention

Method of measurement

Higham table

Intervention groups

1

Description

Intervention 1: Taking Capsules containing 600 mg Calcium once a day from day 15 of menstrual cycle to relieving dysmenorrhea in the following cycle

Category

Treatment - Drugs

2

Description

Intervention 2: Taking Capsules containing 600 mg Calcium and 300 mg magnesium once a day from day 15 of menstrual cycle to relieving dysmenorrhea in the following cycle

Category

Treatment - Drugs

3

Description

Control group: Taking Placebo Capsules once a day from day 15 of menstrual cycle to relieving dysmenorrhea in the following cycle

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dormitories of Aras Branch- Tabriz University of Medical Sciences

Full name of responsible person

salimeh nezamivand-chegini

Street address

City

Aras

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences, Aras branch

Full name of responsible person

Dr. mahmood nazarpour

Street address

Next to Tourism Hotel, Jolfa

City

Jolfa

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Tabriz University of Medical Sciences, Aras branch

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

Tabriz University of Medical Sciences, Aras Unit

Full name of responsible person

Salime Nezamivand-Chegini

Position

Master student of Midwifery

Other areas of specialty/work

Street address

Next to Tourism Hotel, Jolfa

City

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Phone

00

Fax

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Nezamivandsalime@yahoo.com

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences, Nursing & Midwifery Faculty

Full name of responsible person

Sakineh Mohammad-Alizadeh-Charandabi

Position

Assistant professor, PhD in reproductive health

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences - Nursing & Midwifery Faculty

Full name of responsible person

Sakineh Mohammad-Alizadeh-Charandabi

Position

PhD in reproductive health

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

Shariatie Ave.

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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