# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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≥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 dysmenorrhea: a triple-blind randomized controlled trial

**Public title**

The effectiveness of calcium with magnesium and only

calcium on the pain severity and resting lenght 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 mensturation tol 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 Mensturation

**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 menstural 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 menstural cycle to reliefing 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 menstural cycle to reliefing dysmenorrhea in the following cycle
**Category**
Treatment - Drugs

### 3

**Description**
Control group: Taking Placebo Capsules once a day from day 15 of menstural cycle to reliefing 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**
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Next to Tourism Hotel, Jolfa
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00
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Nezamivandsalime@yahoo.com
**Web page address**

## 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

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**Full name of responsible person**
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**Position**
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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*