

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 2026

Comparison of the effects of two different doses of magnesium (150, 300 mg) with placebo on severity of primary dysmenorrhea and amount of menstrual bleeding in female students (18-34 years old)

Protocol summary

Summary

The aim of this randomized controlled trial is to compare effectiveness of two different doses of magnesium on severity of primary dysmenorrhea and amount of Menstrual Bleeding. Sixty eligible persons will be selected for the study and will be randomized using blocks with 3 and 6 cells into three groups (one group will be received tablet of magnesium 150mg, the second group will receive magnesium 300mg and the third one will be placebo). The medications and placebo are quite similar that participants should use them from 15th day of menstrual cycle until complete relief of pain during two months. Ibuprofen 400 mg tablets will be given to participants they will requested to use them in case of they need them and record all medications that they receive. The researcher and participants are not aware of nature of medication or placebo and all medications will be prepared by one pharmacist.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015080319743N2**
Registration date: **2016-01-22, 1394/11/02**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-01-22, 1394/11/02

Registrant information

Name

Masumeh Yaralizadeh

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences,

Country

Iran (Islamic Republic of)

Phone

+98 61 3336 7543

Email address

yaralizadeh.m@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Ahvaz JundiShapur University of Medical Sciences

Expected recruitment start date

2016-01-20, 1394/10/30

Expected recruitment end date

2016-06-19, 1395/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of two different doses of magnesium (150, 300 mg) with placebo on severity of primary dysmenorrhea and amount of menstrual bleeding in female students (18-34 years old)

Public title

Comparison of the effects of two different doses of magnesium with placebo on severity of pain of menstrual and amount of menstrual bleeding

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Single students aged 18-34 years residing in 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. Exclusion criteria: Known serious diseases like epilepsy, severe digestive disorders, cardiovascular, renal diseases, pelvic inflammatory diseases, consumption of oral contraceptive pills in previous 6 months or desire to take them during study and allergy to NSAIDs.

Age

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

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

Sixty participants will be randomized using blocks with 3 and 6 cells into 3 groups, (one group will receive tablet of magnesium 150mg, the second group will receive magnesium 300mg and the third one will receive placebo). This study is a double blind randomized controlled trial therefore the researcher and participants are not aware of nature of medication or placebo tablets will be prepared by one pharmacists.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethical Committee of Ahvaz Jundishapur University of Medical Science

Street address

Ground floor, Department of Research and Information Technology University of Medical Sciences, City University, Ahvaz

City

Ahvaz

Postal code**Approval date**

2015-10-04, 1394/07/12

Ethics committee reference number

AJUMS.REC.1394.347

Health conditions studied**1****Description of health condition studied**

dysmenorrhea

ICD-10 code

N94.4

ICD-10 code description

primary dysmenorrhea

Primary outcomes**1****Description**

Mean severity of menstrual pain

Timepoint

Before and two months after intervention

Method of measurement

Visual Analogue Scale (VAS)

2**Description**

Amount of menstrual bleeding

Timepoint

Before and two months after intervention

Method of measurement

Higham Chart

Secondary outcomes**1****Description**

Need to take additional pain relief drug for dysmenorrhea

Timepoint

Before and two months after intervention

Method of measurement

Number of analgesics used

Intervention groups**1****Description**

Taking Tablets containing 150 mg Magnesium once a day from 15th day of menstrual cycle to complete relief of pain for two months.

Category

Treatment - Drugs

2**Description**

Control group: Taking Tablets containing placebo once a day from 15th day of menstrual cycle to complete relief of pain for two months.

Category

Placebo

3

Description

Intervention 2: Taking Tablets containing 300 mg Magnesium once a day from 15th day of menstrual cycle to complete relief of pain for two months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Chamran University of Ahvaz dormitory

Full name of responsible person

Masumeh Yaralizadeh

Street address

Shahid Chamran University of Ahvaz dormitory,
Golestan Blvd

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Ahvaz JundiShapur
University of Medical Sciences

Full name of responsible person

Dr Nader Saki

Street address

Vice Chancellor for Research, opposite the central
building, Ahvaz Jundishapur University of Medical
Sciences, Golestan Blvd

City

Ahvaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Ahvaz JundiShapur
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

Health Promotion Research Center, Ahvaz
Jundishapur University of Medical Sciences

Full name of responsible person

Salimeh Nezamivand-Chegini

Position

Master degree in midwifery

Other areas of specialty/work

Street address

School of Nursing and Midwifery, Ahvaz Jundishapur
University of Medical Sciences, Golestan Blvd

City

Ahvaz

Postal code

Phone

+98 61 3336 7543

Fax

Email

Nezamivandsalime@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Health Promotion Research Center, Ahvaz
Jundishapur University of Medical Sciences

Full name of responsible person

Masoumeh Yaralizadeh

Position

master degree in midwifery

Other areas of specialty/work

Street address

School of Nursing and Midwifery, Ahvaz Jundishapur
University of Medical Sciences, Golestan Blvd

City

Ahvaz

Postal code

Phone

+98 61 3336 7543

Fax

Email

yaralizadeh.m@ajums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Health Promotion Research Center, Ahvaz
Jundishapur University of Medical Sciences,

Full name of responsible person

Masoumeh Yaralizadeh

Position

Master degree in midwifery

Other areas of specialty/work

Street address

School of Nursing and Midwifery, Ahvaz Jundishapur

University of Medical Sciences, Golestan Blvd

City

Ahvaz

Postal code

Phone

+98 61 3336 7543

Fax

Email

yaralizadeh.m@ajums.ac.ir

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