

# 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  
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##### Postal code

##### Phone

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##### Web page address

### Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Health Promotion Research Center, Ahvaz  
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##### Full name of responsible person

Masoumeh Yaralizadeh

##### Position

master degree in midwifery

##### Other areas of specialty/work

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##### Web page address

### Person responsible for updating data

#### Contact

##### Name of organization / entity

Health Promotion Research Center, Ahvaz  
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##### Full name of responsible person

Masoumeh Yaralizadeh

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**Email**

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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*