

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 2026

### Comparison of oral magnesium and placebo in migraine prophylaxis in pregnancy period

#### Protocol summary

##### Summary

Migraine is one of the most common paroxysmal disorders which can disable patients. In this study we are going to compare the effect of oral magnesium versus placebo on migraine headache in pregnancy period. 64 pregnant women with diagnosis of migraine referred to neurology clinic will be included in this study and randomly will be divided into two groups. 32 patients receive oral magnesium and the other 32 cases receive placebo. We will visit them every 4 weeks up to 12 weeks. We will test serum magnesium level from all patients before and at the end of first and second months after treatment initiation. Severity, duration and frequency of headache, amount of analgesic use and side effects of the drugs in each group will be compared.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016062128559N1**

Registration date: **2016-11-14, 1395/08/24**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-11-14, 1395/08/24

##### Registrant information

###### Name

Nasrin Moradian

###### Name of organization / entity

Kermanshah University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 83 3836 2562

##### Email address

n\_moradian@kums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice-chancellor for research, Kermanshah University of Medical Sciences

##### Expected recruitment start date

2015-10-23, 1394/08/01

##### Expected recruitment end date

2017-02-19, 1395/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of oral magnesium and placebo in migraine prophylaxis in pregnancy period

##### Public title

A comparative study of the effects of oral magnesium versus placebo in migraine prophylaxis in pregnancy period

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria: Diagnosis of migraine according to definition of International Headache Society by a neurologist; at least one year has passed from the time of migraine onset; moderate to severe headache; more than 2 headache attacks per month. Exclusion criteria: Having tension headaches or other non-migraine headaches; overuse of analgesic medications (more than 15 days a month); use of any migraine prophylactic drugs; history of previous or recently infection; history of chronic diseases (diabetes, hypertension, cardiac, vascular, renal and hepatic); use of mineral supplements;

substance and alcohol abuse.

#### Age

No age limit

#### Gender

Female

#### Phase

3

#### Groups that have been masked

No information

#### Sample size

Target sample size: **64**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Kermanshah University of Medical Sciences and Health Services Ethical Comitte

##### Street address

Kermanshah University of Medical Sciences, Shahid Beheshti boulovered, Kermanshah

##### City

Kermanshah

##### Postal code

#### Approval date

2010-09-23, 1389/07/01

#### Ethics committee reference number

KUMS.REC.1394.478

## Health conditions studied

### 1

#### Description of health condition studied

Common Migraine

#### ICD-10 code

G43.0

#### ICD-10 code description

Migraine without aura (common migraine)

### 2

#### Description of health condition studied

Classical Migraine

#### ICD-10 code

G43.1

#### ICD-10 code description

Migraine with aura (classical migraine)

## Primary outcomes

### 1

#### Description

Severity of headache

#### Timepoint

In each migraine attack

#### Method of measurement

Patient will record the headache severity in daily notes as VAS, MIDAS,HITS-6& physician registers them every 4 weeks

### 2

#### Description

Duration of migraine attack

#### Timepoint

In each migraine attack

#### Method of measurement

Patient records the hours of headache in each attack , physician registers them every 4 weeks

### 3

#### Description

Headache frequency

#### Timepoint

In each migraine attack

#### Method of measurement

According to patient records

### 4

#### Description

Analgesic use

#### Timepoint

Every 4 week

#### Method of measurement

According to patient records

## Secondary outcomes

### 1

#### Description

Clinical side effects

#### Timepoint

Every 4 weeks

#### Method of measurement

According to patients notes

## Intervention groups

### 1

#### Description

Magnesium Oxide, 250 mg tablets, 2 times a day (Mino

Company), for 12 weeks

**Category**

Treatment - Drugs

**2**

**Description**

Placebo tablets identical to magnesium tablets in shape and color, 2 times a day, for 12 weeks. Placebo tablets are made in pharmacology faculty of Kermanshah University of Medical Sciences.

**Category**

Placebo

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Neurology Clinic, Emam Reza Hospital

**Full name of responsible person**

Dr Nasrin Moradian

**Street address**

Emam Reza Hospital, Parastar Boulevard, Sorkhelijeh, Kermanshah

**City**

Kermanshah

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Vice-chancellor for research, Kermanshah University of Medical Sciences

**Full name of responsible person**

Mr. Shirzadian

**Street address**

Kermanshah University of Medical Sciences, Building no.2, Shahid Beheshti Boulevard

**City**

Kermanshah

**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, Kermanshah 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**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Nasrin Moradian

**Position**

Neurologist/ Associate Professor

**Other areas of specialty/work**

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00

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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*