

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Evaluation of the effectiveness of magnesium compared with sodium valporate in migraine headache prophylaxis

#### Protocol summary

2015-10-11, 1394/07/19

#### Summary

The aim of this study is to compare the efficacy of magnesium with sodium valproate as prophylactic therapy in adult patients with a diagnosis of migraine headache based on the latest International Headache Society criteria. Study design is randomized, double-blind and prospective. These subject (228 patients) will be entered in the study with a personal satisfaction with regard to the inclusion and exclusion criteria and will be assigned randomly into one out of three groups: 250 mg twice a day magnesium oxide (n=76), 200 mg twice a day sodium valproate (n=76), magnesium oxide (250 mg twice daily) and sodium valproate (200 mg once per day) concurrently (n=76). The study duration from beginning of drug prescription will be 3 month. The primary objective of the study is to compare the frequency and severity of migraine headaches based on Wong-Baker Faces Pain Rating Scale at the end of month 1, 2 and 3 in three groups. Follow up visits will be scheduled every 4 weeks to 12 weeks. To evaluate blood and liver side effects of drugs, CBC, diff, AST, ALT tests will be performed at the start of therapy and the end of 12 weeks of the study. Finally, the severity, frequency, duration of headache, side effects and amount of analgesics needed during a migraine attack will be compared in the two groups.

#### Registrant information

##### Name

Samira Khani

##### Name of organization / entity

Qom University of Medical Science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 25 3783 2370

##### Email address

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#### Recruitment status

**Recruitment complete**

#### Funding source

Qom University of Medical Sciences

#### Expected recruitment start date

2015-11-22, 1394/09/01

#### Expected recruitment end date

2017-05-22, 1396/03/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015081923685N1**

Registration date: **2015-10-11, 1394/07/19**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

#### Scientific title

Evaluation of the effectiveness of magnesium compared with sodium valporate in migraine headache prophylaxis

#### Public title

Comparison of magnesium and sodium valporate in migraine prophylaxis

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

Inclusion criteria: All patients diagnosed with migraine according to the latest International Headache Society

criteria; history of migraine with or without aura for at least 6 months; patient's age between 18-65 years; at least 2 attacks monthly. Exclusion criteria: non-migraine headaches (total number of headache days per month more than 15); overuse of analgesics in migraine attacks (consumption of ergots, NSAIDs and triptans more than 8 days a month); substance and alcohol dependence; illiteracy of patients and their family (unable to fill diaries); pregnancy and breast feeding; any previous history of magnesium or sodium valporate intolerance; history of renal, liver and chronic disease; elevated liver enzymes in the first sampling more than 2 times the normal; neurologic disorders other than migraine; use of supplements that contain magnesium, calcium and riboflavin; use of herbal anti-migraine; use of anti-depressant and anti-psychotic medications.

**Age**

From **18 years** old to **65 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **228**

**Randomization (investigator's opinion)**

Randomized

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

Double blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features**

Block randomization sampling will be used in this study.

**Secondary Ids**

empty

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

Ethics committee of Qom University of Medical Sciences

**Street address**

No. 83, alley 4 ,St. 1.1, Safashahr Ave., Qom

**City**

Qom

**Postal code****Approval date**

2015-09-07, 1394/06/16

**Ethics committee reference number**

IR.MUQ.REC.1394.73

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

Migraine with aura

**ICD-10 code**

G43.1

**ICD-10 code description**

Migraine with aura [classical migraine]

**2****Description of health condition studied**

Migraine without aura

**ICD-10 code**

G43.0

**ICD-10 code description**

Migraine without aura [common migraine]

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

Severity of headache

**Timepoint**

In each migraine attack

**Method of measurement**

The patient will record the severity of headache in each attack based on Wong-Baker Faces Pain Rating Scale using diary and these notes will be registered every 4 weeks by physician.

**2****Description**

duration of headache

**Timepoint**

In each migraine attack

**Method of measurement**

patient will record the hours of headache in each attack , physician will register them every 4 weeks.

**3****Description**

frequency of headaches

**Timepoint**

every 4 weeks

**Method of measurement**

According to patients daily notes

**4****Description**

Analgesic use

**Timepoint**

every 4 weeks

**Method of measurement**

According to patients daily notes

## Secondary outcomes

### 1

#### Description

clinical side effects

#### Timepoint

every 4 weeks

#### Method of measurement

According to patient daily notes

### 2

#### Description

Laboratory side effects (Blood cell count & liver function test changes)

#### Timepoint

before the treatment course and at the end of 12 weeks

#### Method of measurement

lab tests

## Intervention groups

### 1

#### Description

Intervention group 3: Sodium valporate tablet 200 mg once a day orally, for 12 weeks. Magnesium tablet 250 mg twice a day orally, for 12 weeks

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group 2: Sodium valporate tablet 200 mg twice a day orally, for 12 weeks. Placebo tablet once a day orally, for 12 weeks.

#### Category

Treatment - Drugs

### 3

#### Description

Intervention group 1: Magnesium tablet 250 mg twice a day orally, for 12 weeks. Placebo tablet once a day orally, for 12 weeks.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Beheshti Hospital

##### Full name of responsible person

Dr. Seyed Shamsodin Hejazi

##### Street address

Qom, Shahid Beheshti bovd.

##### City

Qom

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research, Qom University of Medical Sciences

##### Full name of responsible person

Hossein Saghafi

##### Street address

Qom

##### City

No. 83, alley 4 ,St. 1.1, Safashahr Ave., Qom

#### 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, Qom 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

School of Medicine , Qom University of Medical Sciences

##### Full name of responsible person

Dr. Samira Khani

##### Position

Pharmacology Ph.D., assistant professor

##### Other areas of specialty/work

##### Street address

East Street No. 2, Moallem Blvd., School of Medicine

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##### Postal code

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## Person responsible for scientific inquiries

### Contact

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**Position**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

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Dr. Samira Khani

**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*