

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of prophylactic Magnesium in functional outcome of patients with migraine headache

#### Protocol summary

##### Summary

(1) Objectives: Aim of this study is to evaluate the probable effect of Magnesium as a prophylactic agent on functional outcome of patients with Migraine headache. (2) Design: Randomized, Double-blind, Placebo-controlled, Single center, Phase 2 trial. (3) Setting and conduct: Patients with migraine headache divided in two groups (55 patients in each group). The intervention group received Propranolol and Magnesium oxide tablet; and the control group received Propranolol and placebo tablet. Number of migraine attacks in month (frequency), headache severity and MIDAS Scale (Migraine Disability Assessment Questionnaires) were assessed after 1 month and 3 month after initiation of drugs. (4) Participants including major eligibility criteria: 110 patients. Major inclusion criteria: Patients with a history of moderate or severe migraine headache with or without aura. Major exclusion criteria: Patients lesser than 15 and more than 50 years old, history of active peptic ulcer; history of diabetes mellitus; asthma; severe depression; heart failure. (5) Intervention: 1- Propranolol tablet 20 mg twice daily and Magnesium oxide tablet 500 mg twice daily in intervention group 2- Propranolol tablet 20 mg twice daily and placebo tablet twice daily in control group. (6) Main outcome measures (variables): 1- Severity of headache 2- Frequency of headache 3- MIDAS score.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013010411995N1**  
Registration date: **2013-04-15, 1392/01/26**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2013-04-15, 1392/01/26

##### Registrant information

###### Name

Sharareh Ghobadi

###### Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 12 3222 8288

###### Email address

ghobadi.sh@ajums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research, Ahvaz Jundishapur University of Medical Sciences.

##### Expected recruitment start date

2012-02-20, 1390/12/01

##### Expected recruitment end date

2012-09-22, 1391/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of prophylactic Magnesium in functional outcome of patients with migraine headache

##### Public title

The effect of Magnesium in migraine prophylaxis

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Patients with history of moderate or

severe migraine headache with or without aura.  
Exclusion criteria: Patient lesser than 15 and more than 50 years old. Women with menstrual migraine; history of active peptic ulcer and severe abdominal discomfort; history of diabetes mellitus; asthma; severe depression; heart failure; Pregnancy; Lactation and patients who suffered from other headaches except migraine.

#### Age

From **15 years** old to **50 years** old

#### Gender

Both

#### Phase

2

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **110**

#### 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

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

##### Street address

Esfand St, Golestan Blvd.

##### City

Ahvaz

##### Postal code

#### Approval date

2011-09-23, 1390/07/01

#### Ethics committee reference number

eth-331

## Health conditions studied

### 1

#### Description of health condition studied

Migraine headache

#### ICD-10 code

G43

#### ICD-10 code description

Migraine

## Primary outcomes

### 1

#### Description

Frequency of headache in month

#### Timepoint

At admission time, after one month and after 3 month

#### Method of measurement

Questionnaire form

## Secondary outcomes

### 1

#### Description

MIDAS score

#### Timepoint

At the admission, and after 3 month

#### Method of measurement

Questionnaire form

## Intervention groups

### 1

#### Description

Intervention1: The patients treat with Propranolol (tablet 20 mg, manufactured by Rooz Daru Company) and Magnesium oxide (tablet 250 mg, manufactured by Abidi Company).

#### Category

Treatment - Drugs

### 2

#### Description

Intervention 2: The patients treat with Propranolol (tablet 20 mg, manufactured by Rooz Daru company) and placebo (same Magnesium tablet, contain lactose, manufactured by Ahvaz College of pharmacy).

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Neurology Department, Golestan Hospital

##### Full name of responsible person

Sharareh Ghobadi, MD

##### Street address

Nosrat St, Golestan Blvd, Golestan Hospital

##### City

Ahvaz

## Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

Vice chancellor for research Ahvaz University of Medical Sciences

**Full name of responsible person**

Mostafa Fegghi, MD

**Street address**

Esfand St, 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 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**

Ahvaz Jundishapur University of Medical Sciences

**Full name of responsible person**

Sharareh Ghobadi, MD

**Position**

Resident of Neurology

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### Person responsible for scientific inquiries

**Contact****Name of organization / entity**

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**Full name of responsible person**

Seyed Ehsan Mohammadianinejad,MD

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### Person responsible for updating data

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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*