

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### The comparison of the effect of magnesium oxide and sodium valproate in migraine prophylaxis: A prospective double blind randomized clinical trial

#### Protocol summary

##### Summary

This study is clinical trial, double blind and cross over. Patients divided to two groups randomly. Participants were randomized in a 1:1 ratio to receive either valproate Na 400 Mg or magnesium oxide 500 mg twice a day for two months. After 4 weeks of washout, participants crossed over to receive the alternative intervention for 2 months. The intensity of migraine headache is evaluated with IV grading and VAS 1-10 and we used questionnaire Migraine Disability Assessment Test that is a test used by doctors to determine how severely migraines affect a patient's life. Inclusion criteria: migraine headache on based criteria HIS; age between 15-65 years old; migraine headache from 6 month ago, headache frequency: more than twice a month with moderate or severe intensity; not used valproate Na and MG within the past 30 days. Exclusion criteria: pregnancy, breastfeeding, renal and hepatic failure, non migraine headache, abused smoke and opium.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201501171666N2**

Registration date: **2015-03-05, 1393/12/14**

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

Last update:

Update count: **0**

##### Registration date

2015-03-05, 1393/12/14

##### Registrant information

###### Name

Narges Karimi

##### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 11 3311 6275

###### Email address

n.karimi@mazums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Mazandaran University of Medical Sciences

##### Expected recruitment start date

2015-03-01, 1393/12/10

##### 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

The comparison of the effect of magnesium oxide and sodium valproate in migraine prophylaxis: A prospective double blind randomized clinical trial

##### Public title

The comparison of the effect of magnesium oxide and sodium valproate in migraine prophylaxis:

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: migraine headache on based criteria IHS; age between 15-65 years old; migraine headache from 6 month ago; headache frequency: more than twice a month with moderate or sever intensity; not used valproate Na and MG within the past 30 days. Exclusion

criteria: pregnancy; breastfeeding; renal and hepatic failure; non migraine headache; smoking and opium and substance abuse.

#### Age

From **15 years** old to **65 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **80**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Crossover

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Mazandaran University of Medical Sceinces

##### Street address

Mazandaran University of Medical Sceinces, Joibar  
three way

##### City

Sari

##### Postal code

#### Approval date

2014-11-19, 1393/08/28

#### Ethics committee reference number

791

## Health conditions studied

### 1

#### Description of health condition studied

Migrain headache

#### ICD-10 code

G43

#### ICD-10 code description

Migraine

## Primary outcomes

### 1

#### Description

Headache intensity

#### Timepoint

2 months after used drug

#### Method of measurement

Questionnaire MIDAS and VAS 1-10

### 2

#### Description

Headache frequency

#### Timepoint

2 months after used drug

#### Method of measurement

Questionnaire MIDAS

### 3

#### Description

Headache duration

#### Timepoint

2 months after used drug

#### Method of measurement

Questionnaire MIDAS

## Secondary outcomes

### 1

#### Description

Headache symptom

#### Timepoint

2 month after use drug

#### Method of measurement

Questionnair

## Intervention groups

### 1

#### Description

Control group: Tab. Valproat Na 200mg BD for 2 month

#### Category

Treatment - Drugs

### 2

#### Description

intervention: tab magnesium oxide 250 mg BD for 2  
month

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Tooba clinic

**Full name of responsible person**

Narges Karimi

**Street address****City**

Sari

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Ahmad Ali Enayati

**Street address**

Moalem square

**City**

Sari

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Mazandaran 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**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Narges karimi

**Position**

Neurologist

**Other areas of specialty/work****Street address**

Bou Ali Sina hospital

**City**

Sari

**Postal code****Phone**

+98 11 3334 3018

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

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**Full name of responsible person**

Narges karimi

**Position**

Neurologist

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drkarimi\_236@yahoo.com

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Narges Karimi

**Position**

Neurologist

**Other areas of specialty/work****Street address****City**

Sari

**Postal code****Phone**

+98 33343018

**Fax****Email****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*