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

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.

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

2015-10-11, 1394/07/19

Registrant information

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Name of organization / entity
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Iran (Islamic Republic of)
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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

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 hedache

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
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Qom, Shahid Beheshti bovd.
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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
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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

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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