Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

The comparison of the effect of magnesium oxide and sodium valproate in migraine prophilaxis: 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: **IRCT2015011716666N2**
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 prophilaxis: A prospective double blind randomized clinical trial

Public title

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

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 Sceinces
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 Sceinces
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
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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