Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 groupl 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
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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 Feghhi, MD

Street address
Esfand St, Golestan Blvd

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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

Other areas of specialty/work

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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