

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

Comparison of oral magnesium and placebo in migraine prophylaxis in pregnancy period

Protocol summary

Summary

Migraine is one of the most common paroxysmal disorders which can disable patients. In this study we are going to compare the effect of oral magnesium versus placebo on migraine headache in pregnancy period. 64 pregnant women with diagnosis of migraine referred to neurology clinic will be included in this study and randomly will be divided into two groups. 32 patients receive oral magnesium and the other 32 cases receive placebo. We will visit them every 4 weeks up to 12 weeks. We will test serum magnesium level from all patients before and at the end of first and second months after treatment initiation. Severity, duration and frequency of headache, amount of analgesic use and side effects of the drugs in each group will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016062128559N1**

Registration date: **2016-11-14, 1395/08/24**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-11-14, 1395/08/24

Registrant information

Name

Nasrin Moradian

Name of organization / entity

Kermanshah University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for research, Kermanshah University of Medical Sciences

Expected recruitment start date

2015-10-23, 1394/08/01

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

Comparison of oral magnesium and placebo in migraine prophylaxis in pregnancy period

Public title

A comparative study of the effects of oral magnesium versus placebo in migraine prophylaxis in pregnancy period

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Diagnosis of migraine according to definition of International Headache Society by a neurologist; at least one year has passed from the time of migraine onset; moderate to severe headache; more than 2 headache attacks per month. Exclusion criteria: Having tension headaches or other non-migraine headaches; overuse of analgesic medications (more than 15 days a month); use of any migraine prophylactic drugs; history of previous or recently infection; history of chronic diseases (diabetes, hypertension, cardiac, vascular, renal and hepatic); use of mineral supplements;

substance and alcohol abuse.

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **64**

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

Kermanshah University of Medical Sciences and Health Services Ethical Comitte

Street address

Kermanshah University of Medical Sciences, Shahid Beheshti boulovered, Kermanshah

City

Kermanshah

Postal code

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

KUMS.REC.1394.478

Health conditions studied

1

Description of health condition studied

Common Migraine

ICD-10 code

G43.0

ICD-10 code description

Migraine without aura (common migraine)

2

Description of health condition studied

Classical Migraine

ICD-10 code

G43.1

ICD-10 code description

Migraine with aura (classical migraine)

Primary outcomes

1

Description

Severity of headache

Timepoint

In each migraine attack

Method of measurement

Patient will record the headache severity in daily notes as VAS, MIDAS,HITS-6& physician registers them every 4 weeks

2

Description

Duration of migraine attack

Timepoint

In each migraine attack

Method of measurement

Patient records the hours of headache in each attack , physician registers them every 4 weeks

3

Description

Headache frequency

Timepoint

In each migraine attack

Method of measurement

According to patient records

4

Description

Analgesic use

Timepoint

Every 4 week

Method of measurement

According to patient records

Secondary outcomes

1

Description

Clinical side effects

Timepoint

Every 4 weeks

Method of measurement

According to patients notes

Intervention groups

1

Description

Magnesium Oxide, 250 mg tablets, 2 times a day (Mino

Company), for 12 weeks

Category

Treatment - Drugs

2

Description

Placebo tablets identical to magnesium tablets in shape and color, 2 times a day, for 12 weeks. Placebo tablets are made in pharmacology faculty of Kermanshah University of Medical Sciences.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Neurology Clinic, Emam Reza Hospital

Full name of responsible person

Dr Nasrin Moradian

Street address

Emam Reza Hospital, Parastar Boulevard, Sorkhelijeh, Kermanshah

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for research, Kermanshah University of Medical Sciences

Full name of responsible person

Mr. Shirzadian

Street address

Kermanshah University of Medical Sciences, Building no.2, Shahid Beheshti Boulevard

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Kermanshah

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, Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Nasrin Moradian

Position

Neurologist/ Associate Professor

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