Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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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Iran (Islamic Republic of)

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+98 83 3836 2562

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n_moradian@kums.ac.ir

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 form 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 Servises Ethical Comitte

Street address
Kermanshah University of Medical Sciences, Shahid Beheshti boulvered, 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 (Minoo

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

City

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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Person responsible for scientific 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