Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Metoclopramide and Magnesium sulphate versus metoclopramide alone in managing acute migraine

Protocol summary

Study aim
Evaluate the magnesium sulfate, as an adjuvant treatment, in managing acute migraine.
Design
Double-blind clinical trial parallel, Randomized
Settings and conduct
In this randomized clinical trial study, patients with migraine referred to Ahvaz Golestan Hospital emergency department، will be randomly divided into two equal groups using block randomization method, Group A will be received 2 g intravenous infusion(I.V) Magnesium sulfate along with 10 mg metoclopramide. and group B will be received 10 mg metoclopramide and placebo. The pain level will be measured by VAS at baseline, 15, 30 and 45 minutes after intervention
Participants/Inclusion and exclusion criteria
Patients with confirmed migraine diagnosis and pain scores more than 4 were included. While, Those with any history of drug adverse reactions, Pregnancy, and lactation, Renal failure, and allergy to magnesium sulfate or metoclopramide were excluded from the study.
Intervention groups
Patients in group A will receive 2 g intravenous infusion(I.V) Magnesium sulfate along with 10 mg metoclopramide. Patients in group B will receive 10 mg metoclopramide and placebo.
Main outcome variables
Headache pain level

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20190504043470N1**
Registration date: **2019-08-04, 1398/05/13**
Registration timing: **prospective**
Last update: **2019-08-04, 1398/05/13**
Update count: **0**
Registration date
2019-08-04, 1398/05/13

Registrant information
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Abbas Khosravi
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-09-21, 1398/06/30
Expected recruitment end date
2020-03-15, 1398/12/25
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Metoclopramide and Magnesium sulphate versus metoclopramide alone in managing acute migraine

Public title
Study of the therapeutic effects of magnesium sulfate in patients with acute migraine
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:

Confirmed diagnosis of migraine Pain scores more than 4

Exclusion criteria:

History of drug adverse reactions Pregnancy Lactation Renal failure

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be performed using block randomization method based on four permutation blocks.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patients know they are participating in a study that is aimed to compare the efficacy and side effects of Metoclopramide and Magnesium sulfate versus metoclopramide and placebo in the management of migraine but they are not informed that they receive which drugs. The physician who evaluates the clinical status of patients and the nurse who injects the drug are not aware of the medication that patients receive

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical commite of Jundishapur University of Ahvaz

Street address

Golestan

City

Ahvaz

Province

Khouzestan

Postal code

6455134358

Approval date

2017-11-28, 1396/09/07

Ethics committee reference number

IR.AJUMS.REC.1396.1142

Health conditions studied

1

Description of health condition studied

Migraine

ICD-10 code

G43

ICD-10 code description

Migraine

Primary outcomes

1

Description

Headache pain score

Timepoint

0, 15, 30, 45 minutes after treatment

Method of measurement

VAS questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 2 g intravenous infusion(I.V) Magnesium sulfate along with 10 mg metoclopramide

Category

Treatment - Drugs

2

Description

Intervention group: 10 mg metoclopramide I.V injection and placebo

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Imam Khomeini Hospital

Full name of responsible person

Mojtaba Sasani

Street address

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran
Full name of responsible person
Mohammad Badvi
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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 Jundishapur University of Medical Sciences, Ahvaz, Iran
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available