Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effect of magnesium sulfate along with a 3-drug regimen (keturolac, plazil and dexamethasone) on the control of acute migraine attacks .

Protocol summary

Study aim

Investigating the effect of magnesium sulfate along with 3-drug regimen (keturolac, plazil and dexamethasone) on controlling acute migraine attacks

Design

This randomized clinical trial study is conducted in a double-blind manner (participants and researchers are not aware of the type of drug prescribed). The method of assigning the intervention to patients is randomly and by the method of randomized permutation blocks with random block sizes of 4, 6 and 8 (using the table related to random permutations)

Settings and conduct

This study will be conducted in Golestan and Razi Hospital, Ahvaz in 1403. which is a randomized and double-blind study on the effect of intravenous Ketorlac and Plazil and intravenous dexamethasone and intravenous Ketorlak and Plazil and dexamethasone with intravenous magnesium sulfate on pain reduction.

Participants/Inclusion and exclusion criteria

Inclusion criteria include patients with migraine headaches aged 18 to 60 who referred to the emergency room. Exclusion criteria: 1. History of sensitivity or allergy to study drugs, 2. Presence of chronic kidney diseases, 3. Patients using painkillers before entering the study, 4. Severe cardiovascular diseases , 5. Electrolytic and metabolic disorders.

Intervention groups

The group receiving intravenous magnesium sulfate along with Ketorlac and Plazil and intravenous Dexamethasone and the group receiving Ketorlac and Plazil and intravenous Dexamethasone

Main outcome variables

pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240930063211N1**
Registration date: **2024-10-24, 1403/08/03**
Registration timing: **registered_while_recruiting**

Last update: **2024-10-24, 1403/08/03**
Update count: **0**

Registration date

2024-10-24, 1403/08/03

Registrant information

Name

Shayan Beik

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 930 889 8239

Email address

dr.shayanbeik@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-09-29, 1403/07/08

Expected recruitment end date

2025-03-19, 1403/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Investigating the effect of magnesium sulfate along with a 3-drug regimen (keturolac, plazil and dexamethasone) on the control of acute migraine attacks .

Public title
Investigating the effect of magnesium sulfate on the control of acute migraine attacks

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with migraine headaches have a pain score greater than 5 (based on visual analog scale (VAS)). The age of the patients should be between 18 and 60 years Consciousness level equal to 15

Exclusion criteria:
Pregnancy or suspected pregnancy History of alcoholism, sensitivity to morphine or painkillers History of mental illness and depression and recent use of sedatives or antipsychotics and use of calcium channel blockers History of cardiac, kidney, liver and metabolic disease The patient's unwillingness to participate in the study

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **124**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, in order to assign patients to 2 intervention and control groups, the block randomization method is used (the size of each block is 4 patients, the total blocks are 31). In order to generate a random sequence, Epi info software is used. In this study, the hidden direction Sequencing is done using sealed envelopes and allocations are kept hidden until the last moment

Blinding (investigator's opinion)
Double blinded

Blinding description
Due to the double-blindness of the study, throughout the study, the patients, doctors, and nurses who administered the drugs were unaware of all the steps of the research, and the preparation and injection of the drugs was done by two nurses or residents, so that the person preparing the drug was different from the receiving patient. The drug and the injecting nurse were unaware of the type of drug. All drug injection syringes are uniform and randomization and data recording was done by one person (emergency medicine assistant).

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Ahvaz University of Medical Sciences

Street address
Informatics Department,First Floor,Research and Technology Vice-Chancellor,Ahvaz University City

City
Ahvaz

Province
Khouzestan

Postal code
15794-61357

Approval date
2024-09-29, 1403/07/08

Ethics committee reference number
IR.AJUMS.REC.1403.325

Health conditions studied

1

Description of health condition studied
Migraine

ICD-10 code
G43.0

ICD-10 code description
Migraine without aura

Primary outcomes

1

Description
patients with a history of migraine headaches whose pain score was greater than 5 based on the analog visual scale

Timepoint
On arrival, 1 hour and 2 hours after administration of the drug

Method of measurement
visual analog scale (VAS)

Secondary outcomes

1

Description
Measuring the scale of Pain Healing in Patients

Timepoint
On arrival, 1 hour and 2 hours after administration of the

drug

Method of measurement

Hemodynamic disorder is assessed by measuring systolic and diastolic blood pressure using a digital sphygmomanometer, and heart rate using a pulse oximeter or heart monitoring.

Intervention groups

1

Description

Intervention group: 3-drug regimen plus magnesium sulfate (30 mg of ketorolac, 10 mg of plazil and 8 mg of Dexamethasone plus 2 grams of magnesium sulfate 50% in a volume of 100 cc

Category

Treatment - Drugs

2

Description

Control group: 3-drug regimen (30 mg of ketorolac, 10 mg of Plazil and 8 mg of dexamethasone

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan Hospital,Ahwaz city

Full name of responsible person

Ali Wafaq Nematullahi

Street address

Golestan Hospital,Golestan town,Ahwaz city

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mehrnoosh Zakerkish

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ground floor,Research and Technology, Jundishapur University of Medical Sciences and Healthcare Services, Ahvaz Academic City - Vice-Chancellor for,ahvaz

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Grant name

Jundishapur University of Medical Sciences, Ahvaz

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ahvaz University of Medical Sciences

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

Ahvaz University of Medical Sciences

Full name of responsible person

Ali Wafaq Nematullahi

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

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

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

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

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