

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Comparison of the effectiveness of morphine and ketorolac in the treatment of acute migraine attacks in patients referred to emergency department of imam khomeyni hospital of urmia

Protocol summary

Study aim

Determining and comparing the effectiveness of sumatriptan, morphine and ketorolac in the treatment of acute migraine attacks

Design

A double-blind clinical trial that has 3 parallel intervention groups. The method of data randomization is also simple randomization using a random number table (the patient and the researcher will be blind to patient grouping).

Settings and conduct

Patients in the emergency room of Imam Khomeini Hospital will receive Sumatriptan at a dose of 6 mg, Ketorolac at a dose of 30 mg and morphine at a dose of 5 mg. Patients will be monitored while receiving medication with a pulse oximeter. All patients will complete the questionnaire. Patients and researchers are blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age over 18 years, history of migraine more than one year, the experience of 2-10 migraine attacks per month, if the patient is taking a migraine prevention medication, they have not changed it for at least the last three months. Exclusion criteria: Patients who are allergic to the study medications; contraindications to the use of these drugs such as basilar migraine and hemiplegic, cerebrovascular and cardiovascular diseases, uncontrolled blood pressure, taking ergotamine or monoamine oxidase inhibitors, triptans and other serotonin agonists; chronic painful diseases other than migraine, blood dyscrasias, chronic liver, kidney, and lung failure, drug addiction, pregnancy, type 1 and 2 diabetes, lack of recovery and the need to take other medications.

Intervention groups

3 groups, each one will receive one of the drugs sumatriptan, morphine or ketorolac

Main outcome variables

Headache; quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210129050168N1**

Registration date: **2022-05-30, 1401/03/09**

Registration timing: **registered_while_recruiting**

Last update: **2022-05-30, 1401/03/09**

Update count: **0**

Registration date

2022-05-30, 1401/03/09

Registrant information

Name

Mostafa chenari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3237 9671

Email address

mostafachenari@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-21, 1401/02/31

Expected recruitment end date

2022-08-22, 1401/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the effectiveness of morphine and ketorolac in the treatment of acute migraine attacks in patients referred to emergency department of imam khomeyni hospital of urmia

Public title
Comparison of the effectiveness of morphine and ketorolac in the treatment of acute migraine attacks

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
being at least 18 years old having a migraine history for at least 1 year having 2 -10 migraine attacks per month if the patient is receiving a prophylactic medication, they shouldn't have changed or interrupted it at least for the previous 3 months
Exclusion criteria:
The patient is allergic to the studied drugs
Contraindications to the use of these drugs such as basilar migraine(migraine with brainstem aura) and hemiplegic migraine, cerebrovascular and cardiovascular diseases, uncontrolled hypertension, ergotamine-containing drugs and monoamine oxidase inhibitors
Blood dyscrasias Chronic painful diseases other than migraine Chronic hepatic, renal, and pulmonary failure
Drug addiction Pregnancy Type 1 and 2 diabetes

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
To randomize the study, the two drugs are filled into syringes marked with codes (a) for ketorolac and (b) for morphine so that the patient and the researcher are blind to the grouping of patients. The patient will be randomly placed in one of these two groups and will receive the drug and the questionnaires will be filled out while the patient and the researcher do not know about the prescribed medication.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants in the project, adviser and researcher will be blind to the drug used during treatment. But the doctor

will be aware of the drug. The drugs will be filled in similar syringes and in 2 boxes (a) and (b) Only the relevant doctor will be aware of. After the drug injection, the questionnaires will be filled while the patient and the researcher do not know the type of medicine.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Urmia university of medical sciences

Street address

Resalat

City

Urmia

Province

East Azarbaijan

Postal code

5714783734

Approval date

2020-09-15, 1399/06/25

Ethics committee reference number

IR.UMSU.REC.1399.210

Health conditions studied

1

Description of health condition studied

acute migraine attack

ICD-10 code

G43

ICD-10 code description

Migraine

Primary outcomes

1

Description

The effect of medication on reducing pain intensity based on visual analog scale (VAS) questionnaire

Timepoint

0 minutes- 60 minutes -120 minutes

Method of measurement

Ten-point VAS questionnaire based on pain intensity

Secondary outcomes

imamkhomeynihospital@gmail.com

1

Description

effects of headache on a person's quality of life and daily activities, and a score above 50 is nominated as a candidate for migraine.

Timepoint

0 minutes- 60 minutes -120 minutes

Method of measurement

A standard questionnaire to assess demographic characteristics and headache, including disability (test [HIT] -6)

Intervention groups

1

Description

Intervention group: Ketorolac will be injected intravenously as a single 30 mg dose

Category

Treatment - Drugs

2

Description

Intervention group: morphine will be injected intravenously as a single 5 mg dose

Category

Treatment - Drugs

3

Description

Intervention group: Sumatriptan will be injected subcutaneously and in a single dose of 6 mg

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emergency department of Imam Khomeyni hospital of Urmia

Full name of responsible person

Hamidreza Mehryar

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Ershad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Hamdollah Sharifi

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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

Oroumia University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Mostafa Chenari

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

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