

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The comparison of intravenous ketorolac and intravenous metoclopramide analgesic effect in patients with acute migraine headache referring to emergency department.

Protocol summary

Summary

Main purpose: Comparison of intravenous ketorolac and intravenous metoclopramide analgesic effect in patients with acute migraine headache referring to the emergency department during years 2016-2017, Inclusion criteria: Age older than 15 and younger than 70 years; History of migraine headache with or without aura, Exclusion criteria: Age younger than 15 or older than 70 years; Pregnant women; People with stomach ulcers; Renal failure; Liver failure; 100 patients with acute migraine headache are enrolled. Ketorolac and metoclopramide are injected intravenously in each group. We use VAS to determine the severity of headache and nausea and vomiting at times, a moment before the injection, 30 minutes, 60 minutes, 2 hours, 4 hours and 24 hours after the injection in both intravenous ketorolac and metoclopramide groups and using closed questions to determine the severity of vertigo in patients in a moment before the injection, 1 hour and 2 hours after injection in both intravenous ketorolac and metoclopramide groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016010425854N1**
Registration date: **2016-08-21, 1395/05/31**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-08-21, 1395/05/31

Registrant information

Name

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Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapur University of Medical Sciences.

Expected recruitment start date

2016-06-21, 1395/04/01

Expected recruitment end date

2017-03-19, 1395/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of intravenous ketorolac and intravenous metoclopramide analgesic effect in patients with acute migraine headache referring to emergency department.

Public title

Ketorolac and metoclopramide in acute migraine headache.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age older than 15 and younger than 70 years; History of migraine headache with or without

aura. Exclusion criteria: Age younger than 15 or older than 70 years; Duration of headache less than 4 or over 72 hours; Patients who had undergone lumbar puncturation(LP) since last 48 hours; Patients who had a systemic headache; Body temperature more than 38 degrees of Celsius; Neurologic deficit; Allergy or tolerance to drugs of study; Participated in other study; Pregnant women; If the patient within 12 hours before entering to the center, received analgesic drug; Patients who for any reason are used analgesics on a daily basis; Patients who can not communicate verbally; If the patient's lost the consciousness due to alcohol consumption and or other material is gone; People with stomach ulcers and severe digestive problems (especially chronic diarrhea); Renal failure; Liver failure; Patients who suffer simultaneously from headaches other than migraine such as tension headaches or sinusitis; If the patient is receiving anticoagulant (due to drug interactions with ketorolac); If the patient is taking probenecid (due to increasing half-life of ketorolac); If the patient receiving phenothiazines, lithium or anti epileptic drugs (due to drug interactions with metoclopramide); If the patient prior to entering the study have akathisia.

Age

From **15 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

N/A

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**

Ahvaz Jundishapur University of Medical Sciences

Street address

Golestan highway, Ahvaz, Khuzestan, Iran

City

Ahvaz

Postal code

6135715794

Approval date

2016-02-20, 1394/12/01

Ethics committee reference number

IR.AJUMS.Rec.1394.488

Health conditions studied**1****Description of health condition studied**

Acute migraine headache

ICD-10 code

G43

ICD-10 code description

Migraine

Primary outcomes**1****Description**

Severity of headache

Timepoint

A moment before the injection, 30 minutes, 60 minutes, 2 hours, 4 hours and 24 hours after the injection.

Method of measurement

Visual analogue scale

2**Description**

24 hours following up.

Timepoint

24 hours after the injection

Method of measurement

After 24 hours, patients are called and asked them to say the severity of their headache as this follow; severe, moderate, mild headache and without headache.

Secondary outcomes**1****Description**

Severity of vertigo(as a side effect of study medication)

Timepoint

A moment before injection, 1 hours and 2 hours after injection.

Method of measurement

Without vertigo, Mild to moderate vertigo but able to do activities, Sever vertigo and inability to do activities.

Intervention groups**1****Description**

Ketorolac 30 mg intravenous.

Category

Treatment - Drugs

2

Description

Metoclopramide 20 mg intravenous.

Category

Treatment - Drugs

3

Description

Biperidine 5 mg intravenous for prevention of metoclopramide side effects.

Category

Prevention

4

Description

Aquapura 5 cc as placebo of biperidine.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Emergency department of Golestan hospital in Ahvaz

Full name of responsible person

Dr Javad Mozaffari - Assistant professor of emergency medicine

Street address

Emergency medicine office, Emergency department of Golestan hospital

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Student research committee, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran.

Full name of responsible person

Dr Nader Saki

Street address

Room 16, floor, Student Research Committee, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran

City

Ahvaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Student research committee, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran.

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

Ahvaz Jundishapur University of Medical Sciences.

Full name of responsible person

Arslan Tahmasbi

Position

Medicine intern.

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