

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Evaluation of analgesic effects of intravenous metoclopramide versus intravenous ketorolac in patients with primary acute headache (migraines, tension, cluster) in emergency department: a double-blind clinical trial

Protocol summary

Study aim

Evaluation of analgesic effects of IV metoclopramide versus IV ketorolac in patients with primary acute headache (migraines, tension, cluster) in the emergency department

Design

This is a randomized double-blind comparative efficacy trial. 98 patients were randomized into two groups. Randomization was performed by block randomization (size of 5 for blocks), using an online random number generator. For ethical reasons, there is no placebo arm. The study protocol was confirmed by the Ethical Committee of Ahvaz Jundishapur University of Medical Sciences.

Settings and conduct

This study will be done at Golestan and Imam Khomeini hospital of Ahvaz.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients referring to the emergency department with acute primary headache (migraine, tension, cluster) with a minimum age of 18 years old and a maximum of 65 years old. Exclusion criteria: Pregnancy, Nursing mothers, Any active bleeding, CHF, MI history, Parkinson or history of any Extrapyrarnidal Side Effects, Pheochromocytoma, Epilepsy and history of seizure, History of Depression, Allergy to experimented drugs, Painkillers administration before admission to the ED, Systolic Blood pressure under 90mmHg or above 180mmHg, Heart rate under 50 beats/min or above 150 beats/min, Patients taking Antipsychotics, Promethazine, MAO inhibitors, Rivastigmine.

Intervention groups

The patients were randomized into two groups A and B. After receiving the VAS score from them: Group A, 30 mg of ketorolac plus 50 ml of normal saline were infused for 15 minutes. Group B, 10 milligrams of metoclopramide

plus 50 ml of normal saline, were infused over 15 minutes. VAS Score, response to treatment and the side effects were assessed within 15, 30 and 60 minutes after receiving medications.

Main outcome variables

Clinical state, Headache intensity (VAS scoring), Adverse effects.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151103024853N4**

Registration date: **2020-08-13, 1399/05/23**

Registration timing: **retrospective**

Last update: **2020-08-13, 1399/05/23**

Update count: **0**

Registration date

2020-08-13, 1399/05/23

Registrant information

Name

Leila Kouti

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-20, 1397/12/01

Expected recruitment end date

2020-02-20, 1398/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of analgesic effects of intravenous metoclopramide versus intravenous ketorolac in patients with primary acute headache (migraines, tension, cluster) in emergency department: a double-blind clinical trial

Public title

Evaluation of analgesic effects of intravenous metoclopramide versus intravenous ketorolac in patients with primary acute headache

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients referring to the emergency department with acute primary headache (migraine, tension, cluster) Age: minimum 18 years old and maximum 65 years old

Exclusion criteria:

Pregnancy Nursing mothers Any active bleeding CHF (Congestive Heart Failure) MI (Myocardial Infarction) history Parkinson or history of any Extrapyrimal Side Effects Pheochromocytoma Epilepsy and history of seizure History of Depression Allergy to experimented drugs Painkillers administration before admission to the Emergency Department (ED) Systolic Blood pressure under 90mmHg or above 180mmHg Heart rate under 50 beats/min or above 150 beats/min Patients taking Antipsychotics, Promethazine, MAO inhibitors, Rivastigmine

AgeFrom **18 years** old to **65 years** old**Gender**

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample sizeTarget sample size: **98****Randomization (investigator's opinion)**

Randomized

Randomization description

The patients were randomized into two groups A (Ketorolac) and B (Metoclopramide) based on a table of random numbers. Randomization was performed by block randomization (size of 6 for blocks), using online

random number generator (Sealed Envelope)

<https://www.sealedenvelope.com/simple-randomiser/v1/lis>. An independent pharmacist performed randomization in blocks of 6 using an online random number generator. the pharmacist filled syringes with each medication and placed them into sequentially numbered sealed envelopes in the order determined by randomization. The contents of these syringes were clear and indistinguishable. The research associates used these medication envelopes consecutively as successive patients enrolled in the study. Only the pharmacist, who was not in the ED, and whose records were maintained in a distant location, knew the randomly allocated assignments. Input Data: Seed: 29346974825611 Treatment groups: Group A, Group B Block sizes: 6 List length: 200 Output Data: Example 34, 6, 6, Group B

Blinding (investigator's opinion)

Double blinded

Blinding description

An independent pharmacist performed randomization in blocks of 6 using an online random number generator. the pharmacist filled syringes with each medication and placed them into sequentially numbered sealed envelopes in the order determined by randomization. The contents of these syringes were clear and indistinguishable. The research associates used these medication envelopes consecutively as successive patients enrolled in the study. Only the pharmacist, who was not in the ED, and whose records were maintained in a distant location, knew the randomly allocated assignments.

Placebo

Not 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

Ahvaz Jundishapur University of Medical Sciences, Golestan blvd., Ahvaz

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Khouzestan

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61357-15794

Approval date

2019-01-19, 1397/10/29

Ethics committee reference number

IR.AJUMS.REC.1397.783

Health conditions studied

1

Description of health condition studied

Migraine

ICD-10 code

G43

ICD-10 code description

Migraine

2

Description of health condition studied

Tension-type headache

ICD-10 code

G44.2

ICD-10 code description

Tension-type headache

3

Description of health condition studied

Cluster headaches

ICD-10 code

G44.0

ICD-10 code description

Cluster headaches and other trigeminal autonomic cephalgias (TAC)

Primary outcomes

1

Description

Pain Visual Analogue Scale (VAS Scoring)

Timepoint

Baseline, 15, 30, 60 minutes after intervention

Method of measurement

10-cm visual analog pain scale

Secondary outcomes

1

Description

Patients achieved headache freedom in the ED without requiring rescue medication

Timepoint

60 minutes after intervention.

Method of measurement

Patients own statement of Headache freedom.

2

Description

Patients that required rescue medication in the ED.

Timepoint

60 minutes after intervention.

Method of measurement

Minor headache improvement in patients with the discretion of the treating physician.

Intervention groups

1

Description

Intervention group: After receiving the baseline VAS score from patients, 30 mg ketorolac plus 50 ml of normal saline were infused for 15 minutes. VAS Score, response to treatment and the side effects were assessed within 15, 30 and 60 minutes after receiving medication.

Category

Treatment - Drugs

2

Description

Intervention group: After receiving the baseline VAS score from patients, 10 mg metoclopramide plus 50 ml of normal saline were infused for 15 minutes. VAS Score, response to treatment and the side effects were assessed within 15, 30 and 60 minutes after receiving medication.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Golestan Hospital

Full name of responsible person

DR. leila kouti

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2

Recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

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

Dr. Leila Kouti

Position

board certified clinical pharmacist / Assistant

Professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

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Name of organization / entity

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Position

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Professor

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Specialist

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