Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 is 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 Extrapyramidal 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

Iran (Islamic Republic of)

Phone

+98 61 3373 8379

Email address

kouti-l@ajums.ac.ir

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 Extrapyramidal 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
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target 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/lists. 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
City
Ahvaz
Province
Khouzestan
Postal code
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
Street address
golestan,Ahvaz Golestan Hospital
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3374 3001
Email
lkouti.pharmacotherapy@gmail.com

2

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Dr . Leila Kouti
Street address
Imam Khomeini Hospital , 24 metri street, Ahvaz
City
Ahvaz
Province
Khouzestan
Postal code

6135715794

Phone
+98 61 3222 2818

Email
lkouti.pharmacotherapy@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Dr. Leila Kouti

Street address
Ahvaz Faculty of Pharmacy, Golestan street, Ahvaz

City
Ahvaz

Province
Khouzestan

Postal code
6135715794

Phone
+98 61 3373 8380

Email
lkouti.pharmacotherapy@gmail.com

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

Street address
Ahvaz Faculty of Pharmacy, Golestan street, Ahvaz

City
Ahvaz

Province
Khouzestan

Postal code
6135715794

Phone
+98 61 3373 8380

Email
lkouti.pharmacotherapy@gmail.com

Person responsible for scientific 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

Street address
Ahvaz Faculty of Pharmacy, Golestan street, Ahvaz

City
Ahvaz

Province
Khouzestan

Postal code
6135715794

Phone
+98 61 3373 8380

Email
lkouti.pharmacotherapy@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Dr. Leila Kouti

Position
متخصص داروسازی بالینی / استادیار

Latest degree
Specialist

Other areas of specialty/work
Medical Pharmacy

Street address
Ahvaz Faculty of Pharmacy, Golestan street, Ahvaz

City
Ahvaz

Province
Khouzestan

Postal code
6135715794

Phone
+98 61 3373 8380

Fax

Email

lkouti.pharmacotherapy@gmail.com

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