Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jun 2026

Comparison of the effectiveness of two intravenous doses of ketorolac for the treatment of acute renal colic in patients referred to the emergency department

Protocol summary

Study aim

This study designed to compare the effect of two doses of 15 and 30 mg of Ketorolac in the treatment of acute pain in patients referred to renal colic in the emergency department of Khatam-al-Anbia Hospital in Zahedan

Design

A randomized clinical trial with parallel, double-blind,phase2, on 160 patients, block randomization

Settings and conduct

Patients referred to the emergency room of Khatam-al-abia Hospital in Zahedan who will be treated for renal colic based on clinical findings admitted.The diagnosis of renal colic is based on CT-scan without abdominal contrast. Patients are randomly divided into two groups receiving15or 30mg ketorolak(prepared in 5cc syringes with the same appearance) at the beginning of hospitalization. Participants and research evaluator isn't aware of the drug group. In cases where pain control isn't achieved with ketorolac injection, the intravenous morphine rescue dose of 0.1mg/kg will be used as an alternative and the number of morphine rescue doses will be recorded. Vital signs and VAS will be assessed at the time of admission (before drug injection), 20, 40 and 60 minutes after injection.

Participants/Inclusion and exclusion criteria

Patients older than 16 years old with moderate to severe acute renal colic are included. Patients older than 70 years of age; pregnant or lactating; with gastrointestinal problems such as gastritis, peptic ulcer or acute bleeding; hypersensitivity to nonsteroidal anti-inflammatory drugs; unstable vital signs ,and patients using analgesia medications are excluded.

Intervention groups

Patients in both groups are treated with15 mg or 30 mg ketorolac. The effectiveness of the two doses of this drug and its side effects are evaluated , and if there is no response to treatment, the next treatment is the use of morphine.

Main outcome variables

Reduction of numerical pain scale; vital signs; side effects; the need for life-saving pain relief; patient satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201018049062N1**
Registration date: **2020-11-18, 1399/08/28**
Registration timing: **prospective**

Last update: **2020-11-18, 1399/08/28**
Update count: **0**

Registration date

2020-11-18, 1399/08/28

Registrant information

Name
Sheida Mehrdad
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-05, 1399/09/15

Expected recruitment end date

2021-03-19, 1399/12/29

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effectiveness of two intravenous doses of ketorolac for the treatment of acute renal colic in patients referred to the emergency department

Public title
Effect of two doses of ketorolac in the treatment of acute renal colic pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All patients over 16 years of age admitted to the emergency department due to renal colic
Exclusion criteria:
age older than 70 y/o Women during pregnancy or lactation Gastrointestinal problems such as gastritis, peptic ulcer or acute bleeding Allergy to nonsteroidal anti-inflammatory drugs Unstable vital signs (systolic BP less than 90 or more than 180 mm Hg, HR less than 50 or more than 150) Patients with a history of analgesia
Age
From **16 years** old to **70 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **160**
Randomization (investigator's opinion)
Randomized
Randomization description
Samples are randomly divided into two groups of 8 blocks. Thus, according to the order of patient placement in the group of 8 in each block, 4 patients from group A and 4 patients from group B will be randomly placed. Then, when referring, a block is selected, and based on the patient's entry order and the card row in each block, the patient will be assigned to the relevant group.
Blinding (investigator's opinion)
Double blinded
Blinding description
The drug groups will be prepared in doses of 15 mg (group A) and 30 mg (group B) in 5cc syringes with the same appearance. At the beginning of the hospitalization, patients are randomly divided into two groups receiving ketorolac (15 or 30 mg ketorolac). In one group, ketorolac at a dose of 15 mg (group A) is administered intravenously and in the other group, ketorolac at a dose of 30 mg (group B) is used intravenously. The classification of patients and the type of medication used for the people involved in the study are blinded and the researcher evaluating the patients is not aware of the drug group prescribed to patients during the study. For this purpose, all syringes of both groups have the same appearance and volume with the same frequency of use in both groups. Other common treatments also apply to both groups. Therefore, the study will be conducted in a double-blind manner.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Zahedan University of Medical Sciences
Street address
Dr. Hesabi Square - Campus of Medical Sciences
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Approval date
2020-10-11, 1399/07/20
Ethics committee reference number
IR.ZAUMS.REC.1399.309

Health conditions studied

1

Description of health condition studied
Renal Colic
ICD-10 code
N20.0
ICD-10 code description
Calculus of kidney

Primary outcomes

1

Description
Pain intensity score on a numerical pain scale
Timepoint
Measurement of pain intensity at the time of referral (before drug injection), 20, 40 and 60 minutes after drug injection
Method of measurement
Visual Analogue Scale

Secondary outcomes

1

Description
Satisfaction with the type of treatment
Timepoint
60 minutes after receiving the drug
Method of measurement
5 point scale

2

Description
Side effects
Timepoint
60 minutes after drug injection
Method of measurement
Physical examination

3

Description
The need for a life-saving dose
Timepoint
After establishing painlessness
Method of measurement
Frequent administration of morphine rescue dose

4

Description
Heart Rate
Timepoint
20, 40 and 60 minutes after injection
Method of measurement
Number on monitoring

5

Description
Average Blood Pressure
Timepoint
20, 40 and 60 minutes after injection
Method of measurement
Number on monitoring

Intervention groups

1

Description
Intervention group: Ketorolac group with a dose of 15 mg stat
Category
Treatment - Drugs

2

Description
Intervention group: Ketorolac group with a dose of 30 mg stat
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Khatam Al-Anbia Hospital in Zahedan
Full name of responsible person
Athare Nazri Panjaki
Street address
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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
Zahedan 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
Zahedan University of Medical Sciences

Full name of responsible person
Sheida Mehrdad

Position
Emergency Medicine Resident

Latest degree
Medical doctor

Other areas of specialty/work
Emergency Medicine

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All data is potentially shareable after unidentified individuals

When the data will become available and for how long
Access period starts 5 months after the results are published

To whom data/document is available
The data from this study will be available to academic and scientific researchers as well as people working in industry (if needed)

Under which criteria data/document could be used
The data from the present study will be usable for other researchers, provided the source and citation are preserved.

From where data/document is obtainable
Applicants can send their application through the mailing address sheida.mehrdad@zaums.ac.ir Dr. Sheida Mehrdad.

What processes are involved for a request to access data/document
After sending a request to receive the documents to Dr. Sheida Mehrdad, he will check the identity of the applicant and the type of application and will send the documents in less than two weeks

Comments