Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

A comparative study of the effect of intravenous ketorolac and morphine on pain control in patients with renal colic

Protocol summary

Study aim
Determining and comparing the effect of ketorolac and morphine on pain control in patients with renal colic

Design
A randomized, double-blinding clinical trial, with the parallel groups, Phase 2 on 272 patients

Settings and conduct
In this randomized double-blind clinical trial, 272 eligible patients referred to Ayatollah Kashani Hospital in Shahrekord will be included in the study and randomly divided into 2 groups. Patients will be injected with ketorolac in the first group and morphine in the second group. The intervention will be performed in such a way that the patient and the researcher will have no knowledge of the type of intervention and the double-blind conditions will be established. Then the patients' pain score and hemodynamic parameters will be evaluated and compared between the two groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria included age range of 16-65 years, the definitive diagnosis of renal colic, the pain intensity of equal to or more than 7, the non-drug addiction, the patients’ consent to participate in the study. Exclusion criteria included having a history of morphine or ketorolac allergy, pregnancy or suspected pregnancy, breastfeeding, having a history of taking painkillers over the last 4 hours.

Intervention groups
Intervention group 1: For patients in this group, intravenous morphine is prescribed at a dose of 1 mg / kg. Intervention group 2: For patients in this group, intravenous ketorolac is prescribed at a dose of 30 mg.

Main outcome variables
Pain score; Moderate arterial pressure; Heart rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200825048515N40**
Registration date: **2021-09-26, 1400/07/04**
Registration timing: **retrospective**

Last update: **2021-09-26, 1400/07/04**
Update count: **0**

Registration date
2021-09-26, 1400/07/04

Registrant information

Name
Asieh Maghami Mehr

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
2019-10-23, 1398/08/01

Expected recruitment end date
2020-03-20, 1399/01/01

Actual recruitment start date
2019-10-23, 1398/08/01

Actual recruitment end date
2020-03-20, 1399/01/01

Trial completion date
2020-03-20, 1399/01/01

Scientific title
A comparative study of the effect of intravenous ketorolac and morphine on pain control in patients with renal colic

Public title
Comparison of the effect of ketorolac and morphine on pain control in patients with renal colic
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
age range of 16-65 years The definitive diagnosis of renal colic (with renal colic symptoms and the presence of stones confirmed by CT) The weight of 50-100 kg (for the effectiveness of the dose of 30 mg ketorolac) The pain intensity of equal to or more than 7 The non-drug addiction The patients' consent to participate in the study
Exclusion criteria:
Having a history of morphine or ketorolac allergy Pregnancy or suspected pregnancy Breastfeeding Having history of taking painkillers over the last 4 hours Having a history of underlying diseases Having traumatic eye or head injuries Having one kidney or a kidney transplant Having cerebral hemorrhage or the possibility of its occurrence Having mental disorders Having fibromyalgia Having vascular and brain lesions Having coagulation disorders, using angiotensin-converting enzyme (ACE) inhibitor or anticoagulants
Age
From **16 years** old to **65 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **272**
Actual sample size reached: **272**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, 272 eligible patients will be randomly selected. Then random numbers are created by computer software "Random Allocation". These numbers are randomly divided into two groups A (first intervention) and B (second intervention). Each number is written on paper and placed in an envelope. Then each patient is asked to choose an envelope from among the envelopes. According to the selected envelope, the patient will be assigned to one of the two groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, ketorolac and morphine, will be prepared by an emergency medicine specialist and placed in coded packages and delivered daily to the researcher, who will prescribe them without knowing the type of each drug. They do. Also, the person recording the clinical and basic information of the patients as well as the statistical analyst will not be aware of the type of intervention.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahre-Kord University of Medical Sciences
Street address
Shahrekord University Of Medical Sciences, Kashani Blvd
City
Shahrekord
Province
Isfehan
Postal code
8815713471
Approval date
2019-09-22, 1398/06/31
Ethics committee reference number
IR.SKUMS.REC.1398.143

Health conditions studied

1

Description of health condition studied
Renal colic
ICD-10 code
N23
ICD-10 code description
Unspecified renal colic

Primary outcomes

1

Description
Pain score
Timepoint
At the beginning of the study and at 5, 15, 30, 60 and 90 minutes after the intervention
Method of measurement
Visual Analogue Scale (VAS)

Secondary outcomes

1

Description

Mean Arterial Pressure

Timepoint

At the beginning of the study and at 5, 15, 30, 60 and 90 minutes after the intervention

Method of measurement

Monitoring device

2

Description

Hear rate

Timepoint

At the beginning of the study and at 5, 15, 30, 60 and 90 minutes after the intervention

Method of measurement

Monitoring device

Intervention groups

1

Description

First intervention group: For patients in this group, morphine (Iran Darou Pharmaceutical Company) is administered intravenously at a dose of 1 mg/kg.

Category

Treatment - Drugs

2

Description

Second intervention group: For patients in this group, Ketorolac (Iran Darou Pharmaceutical Company) is administered intravenously at a dose of 30 mg.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Kashani Hospital

Full name of responsible person

Seyed Mehdi Pourafzali

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Shahrekord University of Medical Sciences, Kashani street,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Mohammad Karami

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Grant name

Grant code / Reference number

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

No

Title of funding source

Shahrekord 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

Esfahan University of Medical Sciences

Full name of responsible person

Seyed Mehdi Pourafzali

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available