Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of Ketamine and Morphine for Pain Control in Patients With Renal Colic: A Randomized Clinical Trial

Protocol summary

Study aim

This study aims to compare the efficacy and safety of low-dose ketamine versus morphine, both administered in combination with ketorolac, for pain management in patients presenting to the emergency department with renal colic. Pain reduction, time to adequate pain relief, need for rescue analgesia, and adverse events will be evaluated and compared between the two treatment groups.

Design

A randomized, double-blind, parallel-group trial involving 340 patients. Block randomization (size 4, ratio 1:1) will be computer-generated, with allocation concealed using sequentially numbered, opaque, sealed envelopes.

Settings and conduct

The trial will be conducted at Firoozabadi Hospital ED. Patients will be randomized to ketamine or morphine, both with ketorolac. Drugs will be prepared in identical syringes. Patients, treating physicians, outcome assessors, and statisticians will be blinded. Pain scores at 0, 15, 30, 45, and 60 minutes, adverse events, and rescue analgesia will be recorded.

Participants/Inclusion and exclusion criteria

A total of 340 patients aged 18–65 years presenting to the emergency department with renal colic and a pain score greater than 4 on the Visual Analog Scale (VAS) will be enrolled after providing informed consent. Patients who are pregnant, require immediate surgical intervention, or have a history of asthma or schizophrenia will be excluded.

Intervention groups

Patients will be randomly assigned to two groups. The intervention group will receive intravenous ketorolac 30 mg plus intravenous ketamine 0.3 mg/kg. The control group will receive intravenous ketorolac 30 mg plus intravenous morphine 0.1 mg/kg. Rescue analgesia will be provided when indicated according to the study protocol.

Main outcome variables

Change in VAS pain scores at 15, 30, 45, and 60 minutes; time to adequate pain relief (VAS less than 4).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260907070962N1**
Registration date: **2026-11-02, 1405/08/11**
Registration timing: **registered_while_recruiting**

Last update: **2026-11-02, 1405/08/11**
Update count: **0**

Registration date

2026-11-02, 1405/08/11

Registrant information

Name

Mahdieh Khaterizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-10-23, 1405/08/01

Expected recruitment end date

2027-07-22, 1406/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of Ketamine and Morphine for Pain Control in Patients With Renal Colic: A Randomized Clinical Trial

Public title
Comparison of Ketamine and Morphine for Pain Relief in Patients With Kidney Stones

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age between 18 and 65 years Presentation to the emergency department with a diagnosis of renal colic Pain intensity greater than 4 on the Visual Analog Scale (VAS) Provision of informed consent
Exclusion criteria:
1. Pregnancy Need for immediate surgical intervention History of asthma History of schizophrenia

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
4

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **340**

Randomization (investigator's opinion)
Randomized

Randomization description
Individual randomization will be performed using block randomization with a fixed block size of four and a 1:1 allocation ratio. The random allocation sequence will be generated by an independent statistician using Random Allocation Software. After obtaining informed consent, eligible patients will be randomly assigned to either the intervention or control group. Allocation concealment will be ensured using sequentially numbered, opaque, sealed envelopes (SNOSE). The envelopes will be prepared according to the random allocation sequence and opened sequentially after enrollment of each eligible participant.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, participants, treating physicians, outcome assessors, and the data analyst will be blinded to treatment allocation. Study medications will be prepared by a nurse who will not be involved in outcome assessment or data collection. Both medications will be prepared in identical 10-mL syringes, without labels identifying the allocated treatment, and adjusted to the same final volume to maintain a similar appearance. Pain intensity and other study outcomes will be assessed and recorded by a trained researcher who will remain unaware of treatment allocation. Data will be provided to the statistician using coded group identifiers, without revealing the actual treatments. Allocation codes will remain confidential until completion of the study and final analysis and will be disclosed only when medically necessary, such as in the event of a serious adverse reaction. Due to differences in the adverse-effect profiles of the study medications, inadvertent unblinding may occur.

Placebo
Not used

Assignment
Parallel

Other design features
History of opioid use will be recorded as a potential effect modifier, and its influence on treatment response will be evaluated in the statistical analysis. Randomization will be performed independently of opioid use history.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
Firoozabadi Hospital, Fadaiyan -e Islam St.,Shahr-e Rey
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Tehran
Province
Tehran
Postal code
1849794113

Approval date
2026-07-08, 1405/04/17

Ethics committee reference number
IR.IUMS.REC.1405.216

Health conditions studied

1

Description of health condition studied
Unspecified renal colic

ICD-10 code
N23

ICD-10 code description
Unspecified renal colic

Primary outcomes

1

Description

Change in pain intensity from baseline measured by the Visual Analog Scale (VAS).

Timepoint

At baseline and 15, 30, 45, and 60 minutes after intervention.

Method of measurement

Pain intensity will be measured using a 0–10 Visual Analog Scale . Change in pain intensity will be calculated relative to baseline.

Secondary outcomes

1

Description

Need for rescue analgesia (fentanyl)

Timepoint

At 15, 30, 45, and 60 minutes after intervention.

Method of measurement

Recording fentanyl administration (yes/no) if Visual Analogue Scale exceeds 4.

2

Description

Occurrence of adverse events associated with the study medications following intervention.

Timepoint

At 15, 30, 45, and 60 minutes after intervention.

Method of measurement

Recording nausea, vomiting, dizziness, dysphoria, hallucinations, agitation, decreased consciousness, blood pressure changes, tachycardia, oxygen desaturation, and respiratory depression through clinical assessment and vital sign monitoring. (yes/no for each event).

3

Description

Time required to achieve adequate pain control following study drug administration.

Timepoint

15, 30, 45, and 60 minutes after intervention.

Method of measurement

Recording the first assessment time at which the pain score is 3 or less on the Visual Analog Scale, in minutes.

4

Description

Hospital admission rate following the study intervention.

Timepoint

At final emergency department disposition.

Method of measurement

Recording hospital admission status based on the treating physician's final decision (yes/no).

5

Description

Time from study drug administration to the need for rescue analgesia.

Timepoint

At 15, 30, 45, and 60 minutes after intervention.

Method of measurement

Recording the time of first intravenous fentanyl administration for a pain score of 4 or higher on the Visual Analog Scale, in minutes.

6

Description

مدت زمان حضور بیمار در بخش اورژانس از زمان ویزیت اولیه تا ترخیص.

Timepoint

From initial physician assessment to emergency department discharge.

Method of measurement

Calculating the interval between initial physician assessment and emergency department discharge, in minutes.

Intervention groups

1

Description

Intervention group: Patients in this group receive intravenous ketorolac 30 mg plus intravenous ketamine 0.3 mg/kg body weight.

Category

Treatment - Drugs

2

Description

Intervention group: Patients in this group receive intravenous ketorolac 30 mg plus intravenous morphine 0.1 mg/kg body weight.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozabadi Hospital

Full name of responsible person

Mahdieh Khaterizadeh

Street address

Firoozabadi Hospital, Fadayian-e Islam Street, near Shahr-e Rey Square, Shahr-e Rey, Tehran, Iran.

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Sponsors / Funding sources

1

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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
Iran 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
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Person responsible for updating data

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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