

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Comparison of the Effectiveness of Intranasal Ketamine, Intravenous Morphine Sulfate, and Intravenous Ketorolac in Reducing the Pain of the Renal Colic Patients

Protocol summary

Study aim

Determining the comparative effect of intranasal ketamine, intravenous morphine and intravenous ketorolac in reducing pain in patients with renal colic.

Design

A phase 4 randomized, double-blind, parallel-group, controlled clinical trial on 99 patients. The rand function of Excel was used for randomization.

Settings and conduct

9 patients with renal colic referred to Shohada Ashayer Hospital in Khorramabad who are randomly assigned to treatment with morphine sulfate, ketamine or ketorolac. Patients' pain intensity is evaluated at 15, 30, 45 and 60 minutes after drug administration. Patients, drug-injecting nurses, and pain-asking physician are blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients referred to the emergency department of Shohada Ashayer Hospital from August 23 to September 22, 2023 who have the following conditions: 1. Patients over 18 years old 2. Having symptoms of renal colic: pain on one or both sides of the patient 3. Diagnosis of kidney stone in CT scan or sonography Exclusion criteria: 1. Pregnant women 2. Addiction to opioids 3. History of allergy to morphine, ketamine or ketorolac 4. Nasal obstruction 5. Systolic blood pressure higher than 180 or lower than 90 mmHg 6. Respiratory distress 7. Decreased level of consciousness 8. Patients who do not have the necessary cooperation 9. History of gastrointestinal bleeding 10. Asthma patients 11. Receiving medication in the past 48 hours

Intervention groups

For patients in group A, 1mg/kg of ketamine intranasally and 5cc of normal saline intravenously, for patients in group B, 0.1mg/kg of morphine sulfate intravenously and 5cc of normal saline intranasally, and for patients in group C, 60mg of ketorolac intravenously and 5cc of

normal saline intranasally will be injected.

Main outcome variables

Pain intensity based on Visual Analogue Scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230718058838N1**

Registration date: **2023-07-20, 1402/04/29**

Registration timing: **prospective**

Last update: **2023-07-20, 1402/04/29**

Update count: **0**

Registration date

2023-07-20, 1402/04/29

Registrant information

Name

Seyed Mobin Nouredini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-23, 1402/06/01

Expected recruitment end date

2023-09-23, 1402/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effectiveness of Intranasal Ketamine, Intravenous Morphine Sulfate, and Intravenous Ketorolac in Reducing the Pain of the Renal Colic Patients

Public title

Comparison of the Effectiveness of Intranasal Ketamine, Intravenous Morphine Sulfate, and Intravenous Ketorolac in Reducing the Pain of the Renal Colic Patients in the Emergency Department of Shohadeye Ashayer Hospital of Khorramabad: A Randomized Controlled Trial

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

More than 18 years old Renal colic symptoms existence: unilateral or bilateral flank pain Sign of nephrolithiasis in CT scan or Ultrasound imaging

Exclusion criteria:

Pregnant female Opioid addiction Sensitivity to Morphine sulfate, Ketorolac or Ketamine Nasal obstruction Systolic blood pressure upper than 180mmHg or lesser than 90mmHg Respiratory distress Loss of conscious Patient with no enough cooperation Past medical history of GI bleeding Past medical history of Asthma Medication using during last 48hours

Age

From **18 years** old

Gender

Both

Phase

4

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **99**

Randomization (investigator's opinion)

Randomized

Randomization description

We will stratify the patient into three groups according to the severity of the pain (1 to 4, 5 to 7 & 8 to 10), then we will use block randomization in each of these groups for finding the members of each prescription group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patients will be randomly divided into three groups. For patients in group A, 1mg/kg of ketamine intranasally and 5cc of normal saline intravenously will be prescribed, in patients in group B, 0.1mg/kg of morphine sulfate intravenously and 5cc of normal saline intranasally will be used, and in patients in group C, 60mg of ketorolac intravenously and 5cc of normal saline intranasally will

be injected. In injecting these drugs, a group of nurses will prepare the prescribed drugs in 5cc syringes according to the pre-designed block randomization method, and if the drug fills less than the syringe volume, they will dilute it with distilled water to reach 5cc volume and without informing the contents, only by specifying the route of drug injection, they will provide it to another group of nurses who are responsible for injecting the drug. It should be noted that patients will not be informed of the type of drug prescribed. The pain level of patients before drug injection and at minutes 15, 30, 45 and 60 after drug administration will be evaluated based on the VAS scale, the responsibility of pain score assessment in all patients will be performed by an experienced specialist physician who is not aware of the type of drug prescribed in the patient and finally the difference between the VAS score before drug administration and the specified times after drug administration will be used as a criterion for evaluating the success of drugs in reducing pain.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Lorestan University of Medical Sciences

Street address

Moalem ave

City

Khorramabad

Province

Lorestan

Postal code

6813833946

Approval date

2023-07-15, 1402/04/24

Ethics committee reference number

IR.LUMS.REC.1402.126

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 severity in the renal colic patients

Timepoint

Before drug injection and 15, 30, 45 & 60 minute after injection

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intranasal injection of 1mg/kg ketamine & 5cc intravenous normal saline

Category

Treatment - Drugs

2

Description

Control group: Intravenous injection of 0.1mg/kg ketamine & 5cc intranasal normal saline

Category

Treatment - Drugs

3

Description

Control group: Intravenous injection of 60mg ketorolac & 5cc intranasal normal saline

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada ashayer hospital

Full name of responsible person

Hamzeh hasani

Street address

Enghelab Ave, Khorramabad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

Bahram delfan

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publicrelation@lums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Khoram-Abad 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

Khoram-Abad University of Medical Sciences

Full name of responsible person

Seyed Mobin Nouredini

Position

دانشجو

Latest degree

A Level or less

Other areas of specialty/work

Medical Education

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Latest degree

A Level or less

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Position

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Latest degree

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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

The whole data can be shared after making individuals unidentifiable.

When the data will become available and for how long

Access start 6 months after publication of results.

To whom data/document is available

Access is available for academic and scientific workers.

Under which criteria data/document could be used

Using the data is not allowed by others.

From where data/document is obtainable

Access to data is possible by sending an email to the research committee of Lorestan University of Medical Sciences.

What processes are involved for a request to access data/document

After sending an email to the research committee of Lorestan University of Medical Sciences via academic email, the relevant data will be sent to the applicant within a maximum of one week

Comments