

# 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

+98 66 3335 1530

##### Email address

mobinnouredini@gmail.com

##### 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

##### City

Khorramabad

##### Province

Lorestan

##### Postal code

6813833946

##### Phone

+98 66 3323 6401

##### Email

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Khoram-Abad University of Medical Sciences

##### Full name of responsible person

Bahram delfan

##### Street address

Moalem Ave, Khorramabad

##### City

khorrabad

##### Province

Lorestan

##### Postal code

6813833946

##### Phone

+98 66 3330 0661

##### Email

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

##### Street address

Keshavarzi Alley, Police Ave, Khorramabad

##### City

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##### Province

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##### Postal code

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**Phone**

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**Email**

mobinnouredini@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Khoram-Abad University of Medical Sciences

**Full name of responsible person**

Seyed Mobin Nouredini

**Position**

Medical student

**Latest degree**

A Level or less

**Other areas of specialty/work**

Medical Education

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Khoram-Abad University of Medical Sciences

**Full name of responsible person**

Seyed Mobin Nouredini

**Position**

Medical student

**Latest degree**

A Level or less

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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**