

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 2026

### Comparison of the analgesic effect of nebulized Ketamine versus intravenous Ketorolac in reducing pain of patients with renal colic who refer to emergency department

#### Protocol summary

##### Study aim

Comparison of analgesic effect of nebulized Ketamine vs IV Ketorolac in reducing pain of patients with renal colic.

##### Design

Phase 3, randomized, triple-blind, controlled clinical trial with parallel group design of 108 patients.

##### Settings and conduct

Therapeutic trial in the emergency department of Imam Hossein hospital in Shahroud as a triple-blind (patient, responsible for outcome assessment and statistical analyzer). Assign the code to each of the treatment groups that the nurse is aware of. Patients with renal colic with inclusion criteria are randomly admitted to the intervention or control group. For the intervention group, nebulization 0.5 mg per kg of Ketamine + injection of 1 cc of normal saline and for the control group injection of 1 mg/kg of Ketorolac + nebulization 0.5 cc/kg of distilled water is prescribed. If the pain is not controlled after 2 hours, 0.1 mg/kg of Morphine is injected. The patient's pain is measured according to the NRS and side effects before the study, 5, 15, 30 and 60 minutes after the study. Measuring patient satisfaction at the end of the study.

##### Participants/Inclusion and exclusion criteria

Inclusion: between 20 to 70 years old, Pain in one side flank. Exclusion: Unstable (SBP<90, HR>100 or HR<60, fever), pregnant, has one kidney, acute abdominal signs (tenderness, guarding, rebound tenderness), hasn't informed consent, history of addiction, history of take analgesic during the previous 6 hours.

##### Intervention groups

Intervention group: The nurse nebulizes 0.5mg/kg Ketamine and injects 1cc normal saline for each patient. Control group: The nurse injects 1mg/kg of Ketorolac and 0.5cc/kg of distilled water is nebulizes for each patient.

##### Main outcome variables

Score of renal colic pain in numeric rating scale

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220201053906N1**

Registration date: **2022-06-05, 1401/03/15**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-06-05, 1401/03/15**

Update count: **0**

##### Registration date

2022-06-05, 1401/03/15

##### Registrant information

##### Name

Hossein Amiri largani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 23 3234 2000

##### Email address

amirilargani@shmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-05-22, 1401/03/01

##### Expected recruitment end date

2022-11-22, 1401/09/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Comparison of the analgesic effect of nebulized Ketamine versus intravenous Ketorolac in reducing pain of patients with renal colic who refer to emergency department

## Public title

Evaluation of the effect of Ketamine by nebulizer in reducing pain caused by renal colic.

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients 20-70 years old With acute pain in one side flank Has informed consent

### Exclusion criteria:

Unstable patients ( SBP<90, HR>100 or HR<60, fever) Pregnant or Suspicion of pregnancy Single kidney Hasn't informed consent or unable to have informed consent Want to discharge before ending the study(2 hours after starting the study) History of addiction History of take analgesic at least 6 hours Symptom or sign of acute abdominal (tenderness, guarding, rebound) Need Rescue dose before ending of the study

## Age

From **20 years** old to **70 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

## Sample size

Target sample size: **108**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Patient will be randomly divided into 2 groups of 54, using random allocation software. Treatments will start randomly from the first patient who has inclusion criteria. First, the numbers 1 to 108 will be written on 108 envelopes. There is a sheet containing the code of each patient's treatment in each envelope, which is defined by the random allocation software that determines the treatment of each patient. Every patient with inclusion criteria will be allocated an envelope.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

This study is double-blinded. To blind the patient, the pain assessor and statistical analyzer a code will be allocated for each patient. Just emergency medicine specialist and nurse know the meaning of the cods. To make the patient blind, Ketorolac syringe and a placebo nebulizer or Ketamine nebulizer and a placebo syringe will be prepared. After collecting the data, the data will be entered into SPSS using random allocation software codes and will be provided to the statistical analyzer for analysis. Pain is a mental variable, therefore, making the

pain assessor blind is important. So, the pain assessor who assesses the intensity of pain doesn't know the codes of each treatment, just knows the treatment code of each patient.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Shahroud University of Medical Sciences

##### Street address

No. 2, Sixth Alley, Shahid Rajaei Ave.,

##### City

Shahroud

##### Province

Semnan

##### Postal code

3616675189

#### Approval date

2022-01-28, 1400/11/08

#### Ethics committee reference number

IR.SHMU.REC.1400.235

## 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

Score of renal colic pain in NRS

#### Timepoint

Before starting the study, 5, 15, 30 and 60 minutes after starting the study

#### Method of measurement

Numeric rating scale (NRS)

## Secondary outcomes

## 1

### **Description**

Patient satisfaction with pain control

### **Timepoint**

2 hours after the start of the study

### **Method of measurement**

Asking verbal

## 2

### **Description**

Side effects of the treatments

### **Timepoint**

Before starting the study, 5, 15, 30, 60 minutes after starting the study and if the patient has been in the hospital for more than 2 hours; At the time of discharge of the patient.

### **Method of measurement**

Medical history and physical examination

## 3

### **Description**

Duration of the patient's presence in the emergency department

### **Timepoint**

At the time of discharge of the patient

### **Method of measurement**

Clock

## **Intervention groups**

## 1

### **Description**

Intervention group: The nurse nebulizes 0.5 mg/kg Ketamine and injects 1 cc / kg normal saline For the patient who is a member of the intervention group.

### **Category**

Treatment - Drugs

## 2

### **Description**

Control group: The nurse injects 1mg/kg of Ketorolac and 0.5 cc / kg of distilled water is nebulizes for the patient in the control group.

### **Category**

Treatment - Drugs

## **Recruitment centers**

## 1

### **Recruitment center**

#### **Name of recruitment center**

Imam Hosein hospital in shahrood

#### **Full name of responsible person**

Hsoein Amiri largani

#### **Street address**

Imam Hosein hospital, Imam Hosein sq.

#### **City**

Shahrood

#### **Province**

Semnan

#### **Postal code**

3616951835

#### **Phone**

+98 23 3234 2000

#### **Email**

imamhosein@shmu.ac.ir

#### **Web page address**

## **Sponsors / Funding sources**

## 1

### **Sponsor**

#### **Name of organization / entity**

Shahrood University of Medical Sciences

#### **Full name of responsible person**

Vice chancellor for research and technology

#### **Street address**

Vice chancellor for research and technology, Shahrood University of Medical Sciences and Health Services, 7 Tir Sq.

#### **City**

Shahrood

#### **Province**

Semnan

#### **Postal code**

3616951835

#### **Phone**

+98 23 3239 6714

#### **Email**

vcr@shmu.ac.ir

#### **Grant name**

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

Shahrood 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**

Shahrood University of Medical Sciences

#### **Full name of responsible person**

Yasaman Safari

#### **Position**

Medical intern

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

**Street address**

Narges dirmitory, Shahid Fakori Blvd.

**City**

Shahrood

**Province**

Semnan

**Postal code**

3616911151

**Phone**

0098 21 2231020

**Email**

asemon.violet@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahroud University of Medical Sciences

**Full name of responsible person**

Hosein Amiri largani

**Position**

Associate Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Emergency Medicine

**Street address**

Emergency department, Imam Hosein hospital, Imam Hosein Sq.

**City**

Shahrood

**Province**

Semnan

**Postal code**

3616951835

**Phone**

+98 23 3234 2000

**Email**

amirilargani@shmu.ac.ir

**Person responsible for updating data****Contact****Name of organization / entity**

Shahroud University of Medical Sciences

**Full name of responsible person**

Sepide Mahdavi

**Position**

Faculty member

**Latest degree**

Master

**Other areas of specialty/work**

Epidemiology

**Street address**

Shahroud University Of Medical Sciences, 7 tir sq.

**City**

Shahrood

**Province**

Semnan

**Postal code**

3614773943

**Phone**

+98 23 3239 3961

**Email**

s.mahdavi88@gmail.com

**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