

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of the Effectiveness of Intranasal Ketamine vs. Intravenous Ketorolac on Renal Colic Pain in Nephrolithiasis Patients

#### Protocol summary

Renal colic pain intensity; side effects

##### Study aim

The aim of this study is comparison of the effectiveness of intranasal ketamine vs. intravenous ketorolac on renal colic pain.

##### Design

In this double-blind randomized controlled clinical trial (phase 2) with parallel group, one hundred (100) patients older than 18 years old allocated in one of two groups and received single dose of the intervention or placebo, with blocked randomization method.

##### Settings and conduct

Patients referring to Department of Emergency Medicine, Imam Khomeini Hospital, Ahvaz suffering from renal colic with pain intensity greater than or equal to 5 out of 10 on the visual analog scale (VAS) will be allocated in one of two groups based on blocked randomization. The control group receive single dose of ketorolac 30mg (1ml) intravenous plus intranasal placebo and intervention group receive single dose of intranasal ketamine (1 mg/kg) and placebo (1 ml) intravenous. Physicians evaluating cases, nurses injecting medication and patients do not know if patients are receiving drug or placebo. Pain intensity and side effects will be measured at 0, 5, 15, 30, 45, 60, 75 and 90 minutes after drug administration.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: patients 18 years old and older; renal colic pain and pain intensity greater than or equal to 5 out of 10 on the visual analog scale (VAS). Exclusion criteria: allergy or contraindication to ketamine; ketorolac or other NSAIDs; patients who are hemodynamically unstable and the history of opium addiction.

##### Intervention groups

The control group receive single dose of ketorolac 30mg (1ml) intravenous plus intranasal placebo and intervention group receive single dose of intranasal ketamine (1 mg/kg) and placebo (1 ml) intravenous.

##### Main outcome variables

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180526039846N1**

Registration date: **2018-06-03, 1397/03/13**

Registration timing: **prospective**

Last update: **2018-06-03, 1397/03/13**

Update count: **0**

##### Registration date

2018-06-03, 1397/03/13

##### Registrant information

##### Name

Ali Khavanin

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3222 2818

##### Email address

khavanin-a@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-08-22, 1397/05/31

##### Expected recruitment end date

2020-03-19, 1398/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Comparison of the Effectiveness of Intranasal Ketamine vs. Intravenous Ketorolac on Renal Colic Pain in Nephrolithiasis Patients

### Public title

Effect of intranasal Ketamine in treatment of nephrolithiasis

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Patients 18 years old and older Renal colic pain The renal stone or sand diagnosis had been confirmed by ultrasound or CT scan evidence. Describes pain to be greater than or equal to 5 out of 10 on the visual analog scale (VAS)

#### Exclusion criteria:

Allergy or contraindication to Ketamine, ketorolac or other NSAIDs Patients who are hemodynamically unstable Breastfeeding or pregnant mothers Patients with language barriers that are unable to describe their pain The history of opium addiction

### Age

From **18 years** old

### Gender

Both

### Phase

2

### Groups that have been masked

- Participant
- Care provider
- Outcome assessor

### Sample size

Target sample size: **100**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Assignment of patients in two groups of test and control will be done by Block Balanced Randomization (BBR) method. The Randomization Sequence will be generated with using the free website at <http://www.randomization.com>.

### Blinding (investigator's opinion)

Double blinded

### Blinding description

The patients know they are participating in a investigation that is aimed to evaluate the analgesic effect of intranasal ketamin on the renal colic but they are not informed that they receive placebo or intranasal ketamin. The physician who evaluates the clinical status of patients and the nurse who injects the drug are not aware of the medication that patients receive.

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

##### Street address

Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd

##### City

Ahvaz

##### Province

Khouzestan

##### Postal code

15794-61357

#### Approval date

2018-05-05, 1397/02/15

#### Ethics committee reference number

IR.AJUMS.REC.1397.071

## Health conditions studied

### 1

#### Description of health condition studied

Calculus of kidney

#### ICD-10 code

N20

#### ICD-10 code description

Calculus of kidney

## Primary outcomes

### 1

#### Description

Renal colic pain

#### Timepoint

At 0, 5, 15, 30, 45, 60, 75 and 90 minutes after drug administration

#### Method of measurement

Visual analog scale

## Secondary outcomes

### 1

#### Description

Side effects

#### Timepoint

At 0, 5, 15, 30, 45, 60, 75 and 90 minutes after drug administration

#### Method of measurement

Clinical observations

## Intervention groups

### 1

#### Description

Single dose of intranasal ketamine (1 mg/kg) and placebo (1 ml) intravenous

#### Category

Treatment - Drugs

### 2

#### Description

Single dose of ketorolac 30mg (1ml) intravenous injection plus intranasal placebo

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Ahvaz Jundishapur University of Medical Sciences

##### Full name of responsible person

Ali Khavanin

##### Street address

Imam Khomeini Hospital, Azadegan Street, Ahvaz

##### City

Ahvaz

##### Province

Khuzestan

##### Postal code

15794-61357

##### Phone

+98 61 4355 4063

##### Email

khavanin-a@ajums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ahvaz University of Medical Sciences

##### Full name of responsible person

Ali Khavanin

##### Street address

Department of Emergency Medicine, Imam Khomeini Hospital, Azadegan St

##### City

Ahvaz

##### Province

Khuzestan

##### Postal code

6193673166

##### Phone

+98 61 3292 1837

##### Email

khavanin-a@ajums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

##### Full name of responsible person

Ali Khavanin

##### Position

Assistant Professor Of Emergency Medicine

##### Latest degree

Specialist

##### Other areas of specialty/work

Emergency Medicine

##### Street address

Department of Emergency Medicine, Imam Khomeini Hospital, Azadegan Street

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Ahvaz University of Medical Sciences

##### Full name of responsible person

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Ahvaz University of Medical Sciences

**Full name of responsible person**

Ali Khavanin

**Position**

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**Latest degree**

Specialist

**Other areas of specialty/work**

Emergency Medicine

**Street address**

Department of Emergency Medicine, Imam Khomeini  
Hospital, Azadegan Street

**City**

Ahvaz

## 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