

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jun 2026

### Comparison of the efficacy of IV ketamine with IV morphine and IV ketorolac in patients with renal colic

#### Protocol summary

##### Study aim

Rapid reduction and relief of pain is one of the primary goals of patients referred to the emergency department of medical centers. The use of rapid-acting drugs that are associated with the least complication and patient satisfaction, which leads to reducing the length of hospital stay in the emergency room and determining their duties.

##### Design

Clinical trial with 3 groups, parallel, the first group of 42 people receiving ketorolac, the second group of 42 people receiving morphine, the third group of 42 people receiving ketamine.

##### Settings and conduct

a) Admission of patients with initial diagnosis of renal colic to the emergency room of Shahid Madani Hospital in Karaj with inclusion criteria b) 126 patients are randomly divided into 3 groups of 42 (first group: ketamine recipient, second group: ketorolac, third group: intravenous morphine) according to the statistical consultant. c) Before taking the drug, a person will assess the severity of the initial pain using the Numerical Rating Scale (NRS). d) Then the medicine will be prescribed according to the group in which the person is placed (Randomize). (Ketamine group ...)

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: all patients with renal colic pain.  
Exclusion criteria: opium use in the last 6 hours; history of bipolar and psychological disease.

##### Intervention groups

From patients who refer to the emergency department of "Karaj Madani" Hospital with renal colic and have the necessary criteria to enter the study, 126 people are selected and randomly divided into 3 groups of 42 people.

##### Main outcome variables

Pain

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20211023052851N1**

Registration date: **2021-12-19, 1400/09/28**

Registration timing: **retrospective**

Last update: **2021-12-19, 1400/09/28**

Update count: **0**

##### Registration date

2021-12-19, 1400/09/28

##### Registrant information

##### Name

Fereshte Lotfi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8833 1084

##### Email address

l32fereshteh@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-11-08, 1400/08/17

##### Expected recruitment end date

2021-11-21, 1400/08/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the efficacy of IV ketamine with IV morphine and IV ketorolac in patients with renal colic

2021-03-06, 1399/12/16

**Ethics committee reference number**  
IR.ABZUMS.REC.1400.039

**Public title**

The effect of ketamine in improving renal colic pain

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

All patients with renal colic pain

**Exclusion criteria:**

Taking opium drugs in past 6 hours History of bipolar and psychological disease

**Age**

No age limit

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **126**

**Randomization (investigator's opinion)**

Not randomized

**Randomization description**

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

The patient will only be told that we will prescribe painkillers, but only the participant will be unaware of the medication received.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Alborz University of Medical Science

**Street address**

Office of the Ethics Committee-Second Floor-Deputy of Research and Technology-Saffarian Alley-45 meters from Golshahr

**City**

Karaj

**Province**

Alborz

**Postal code**

1411953473

**Approval date**

**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**

The rate of patient pain reduction

**Timepoint**

Will assess the severity of pain and side effects at 5, 15, 30 and 60 minutes after drug administration

**Method of measurement**

The patient is asked to give a score of 10 for the most severe pain he or she has ever experienced, and to rate his or her current pain accordingly.

**Secondary outcomes**

empty

**Intervention groups**

1

**Description**

Intervention group: Patients with renal colic pain who received intravenous ketamine. In this group of patients, 10% ketamine is slowly injected intravenously and the dosage is equivalent to 0.5 mg / kg body weight. This injection is given only once and its therapeutic effects are evaluated 6 hours after the injection. this drug is made by ROTEXMEDICA Pharmaceutical company.

**Category**

Treatment - Drugs

2

**Description**

Control group: Patients with renal colic who received intravenous morphine. Patients in this group receive 3 mg of diluted 1% morphine intravenously and slowly. This injection is given only once and the results are evaluated up to 6 hours after the injection. this drug is made by ROTEXMEDICA Pharmaceutical company.

**Category**

Treatment - Drugs

### 3

#### Description

Control group: Patients with renal colic pain who received intravenous ketorolac. In this group of patients, one 30 mg Ketrolac ampule, equivalent to one ml is injected intravenously. This injection is given only once and Results are evaluated 2 hours after injection. This drug is produced by Raha Pharmaceutical Company.

#### Category

Treatment - Drugs

### Recruitment centers

#### 1

##### Recruitment center

**Name of recruitment center**

Shahid Madani Hospital

**Full name of responsible person**

Fereshteh Lotfi

**Street address**

Jahanshar blvd, karaj,alborz

**City**

Karaj

**Province**

Alborz

**Postal code**

1411953473

**Phone**

+98 21 8833 1084

**Email**

l32fereshteh@gmail.com

### Sponsors / Funding sources

#### 1

##### Sponsor

**Name of organization / entity**

Karaj University of Medical Sciences

**Full name of responsible person**

Dr mohammad reza maghsoudi

**Street address**

Deputy of Research and Technology-Saffarian  
Alley-45 meters from Golshahr

**City**

Karaj

**Province**

Alborz

**Postal code**

1411953473

**Phone**

+98 21 8833 1084

**Email**

dr.maghsoudi.m@gmail.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

Deputy of Research of Karaj 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**

Karaj University of Medical Sciences

**Full name of responsible person**

Mohamad Reza Maghsoudi

**Position**

Emergency medicine specialist

**Latest degree**

Specialist

**Other areas of specialty/work**

Emergency Medicine

**Street address**

Madani hospital, Jahanshahr blvd.

**City**

Karaj

**Province**

Alborz

**Postal code**

1411953473

**Phone**

+98 21 8833 1084

**Email**

dr.maghsoudi.m@gmail.com

### Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Karaj University of Medical Sciences

**Full name of responsible person**

Mohamad Reza Maghsoudi

**Position**

Emergency medicine specialist

**Latest degree**

Specialist

**Other areas of specialty/work**

Emergency Medicine

**Street address**

Madani hospital, Jahanshahr blvd.

**City**

Karaj

**Province**

Alborz

**Postal code**

1411953473

**Phone**

+98 21 8833 1084

**Email**

dr.maghsoodi.m@gmail.com

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

Karaj University of Medical Sciences

**Full name of responsible person**

Fereshte Lotfi

**Position**

Medical student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

**Street address**

Alborz School of Medicine, Campus of the University of Medical Sciences, Above the University of Arts, West Buali, Nabovat Square, Karaj

**City**

Tehran

**Province**

Tehran

**Postal code**

3149969415

**Phone**

+98 21 8833 1084

**Fax****Email**

l32fereshteh@gmail.com

**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**

Data on pain in renal colic patients after ketamine administration after patients were not identified Data on pain in renal colic patients after morphine administration after patients were not identified Data on pain in renal colic patients after administration of ketorolac after patients are not identified

**When the data will become available and for how long**

Access to data 6 months after the publication of the article

**To whom data/document is available**

Researchers workers in medical academic institutions

**Under which criteria data/document could be used**

Allow access to compare with other painkillers as well as scale with pain relief in other diseases

**From where data/document is obtainable**

to this email adress: l32fereshteh@gmail.com

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

The data will be reviewed and submitted within one business week upon request

**Comments**