

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 Ketorolac 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 ketolac 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