

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of analgesic effect of intravenous low dose Ketamine and intravenous ketorolac ,in management of the acute pain in renal colic patients who admitted to the emergency department

Protocol summary

Summary

To compare the analgesic effects of intravenous (IV) ketamine with IV ketorolac in acute renal colic . This is a randomized double blind clinical trial and all patient who come to emergency department with acute renal colic (diagnosed by past history and clinical sign) and signed inform consent form and have not exclusion criteria of the study(unwilling to study participation, drug allergy and ets) , include to the trial. The study population is 126 patients . With block randomization each patients allocated to one of two groups. Group 1, receive 0.6 mg/kg intravenous ketamine as analgesic group2, receive 30 mg intravenous ketorolac as analgesic. All patients will undergo pain intensity measurement by Numeric Rating Scale (NRS) from 0 to 10. At the beginning of study and after 5,15,30,60 and 120 min of intervention we calculate pain level of patients with using of Numeric Rating Scale. We use 0.1 mg/kg morphin sulfat as rescue analgesic if persistent pain . The reduction in Numeric Rating Scale of pain and complications at 0, 5, 15, 30 , 60 , 120 minute and need for rescue analgesia will be recorded and the difference between these values will be evaluated by statistical methods.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017021932660N1**

Registration date: **2017-06-06, 1396/03/16**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-06-06, 1396/03/16

Registrant information

Name

Mozhgan Farmahini Farahani

Name of organization / entity

Tehran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2016-03-19, 1394/12/29

Expected recruitment end date

2017-06-21, 1396/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of analgesic effect of intravenous low dose Ketamine and intravenous ketorolac ,in management of the acute pain in renal colic patients who admitted to the emergency department

Public title

Analgesic effect of intravenous ketamine in patients with renal colic

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: all patient with high clinical suspicious of renal colic; all patient who come with pain and have clinical or lab data of renal colic. Exclusion criteria: age < 18 years; unwilling to study participation; past history of allergy to ketorolac or ketamine; Pregnancy or probable pregnancy; Breast feeding; history of analgesic drug consumption < 4 hours ago; liver; renal or heart failure patients; decrease level of consciousness; mental disability; fibromyalgia; Vascular lesions and brain lesions; History of opium addiction; Psychosis; Refusal of the patients from the participation; Head and eyes trauma

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **126**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Tehran University of Medical Sciences , Department of Medical Research

Street address

No. 1 , North door of Tehran university , Poursina street, Enghelab street Tehran

City

Tehran

Postal code**Approval date**

2015-09-19, 1394/06/28

Ethics committee reference number

IR.TUMS.REC.1394.786

Health conditions studied**1****Description of health condition studied**

Renal colic

ICD-10 code

N20

ICD-10 code description

Calculus of kidney and ureter

Primary outcomes**1****Description**

The pain of kidney stones

Timepoint

0 , 5 , 15 , 30 , 60 , 120 min

Method of measurement

Numeric Rating Scale

Secondary outcomes**1****Description**

Hypertention

Timepoint

5, 15,30,60,120 min after intervention

Method of measurement

Using a questionnaire , Measurement of vital signs

2**Description**

Tachycardia

Timepoint

5, 15,30,60,120 min after intervention

Method of measurement

Using a questionnaire, measurement of vital signs

3**Description**

Nausea

Timepoint

5, 15,30,60,120 min after intervention

Method of measurement

Using a questionnaire

4**Description**

Dizziness

Timepoint

5, 15,30,60,120 min after intervention

Method of measurement

Using a questionnaire

5**Description**

Agitation

Timepoint

5, 15,30,60,120 min after intervention

Method of measurement

Using a questionnaire

Intervention groups

1

Description

In Group A, patients receive a dose of 0.6mg / kg intravenous ketamine. Pain severity base on NRS and complication such as hypertention, Tachycardia ,nausea ,dizziness, agitation , will be recorded at 5th, 15th, 30th ,60th and 120th minute. Persistent pain after receive drug ,0.1 mg/kg of intravenous morphine will be administrated as rescue analgesia .

Category

Treatment - Drugs

2

Description

In Group B, patients receive a dose of 30mg intravenous ketorolac. Pain severity base on NRS and complication such as hypertention, Tachycardia ,nausea ,dizziness, agitation , will be recorded at 5th, 15th, 30th ,60th and 120th minute. Persistent pain after receive drug ,0.1 mg/kg of intravenous morphine will be administrated as rescue analgesia .

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Dr Mozghan Farmahini Farahani

Street address

Sina Hospital , Hsan Abad Square , Imam Khomeini Street , Tehran

City

Tehran

2

Recruitment center

Name of recruitment center

Emam Khomaini Hospital

Full name of responsible person

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Emam Khomaini Hospital , End of Keshavarz Blv , Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical sciences

Full name of responsible person

Shahin Akhund zadeh

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Room 206 , 1th floor , Building 1 , Tehran University of Medical Sciences

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Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Other areas of specialty/work

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty

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

Tehran University of Medical Sciences

Full name of responsible person

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Position

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Other areas of specialty/work