Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

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

Protocol summary

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

Renal colic pain intensity; side effects

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
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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
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Sponsors / Funding sources

1

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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
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Position
Assistant Professor Of Emergency Medicine
Latest degree
Specialist
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Person responsible for updating data

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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