

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Comparison of the therapeutic effects of intranasal ketamine and intravenous fentanyl in the treatment of patients with renal colic

Protocol summary

Study aim

Comparison of therapeutic effects of ketamine intranasal and venous fentanyl in patients with renal colic

Design

Patients will randomly be divided into two groups A and B, and each patient will be assigned a code. Special drug and dosing are provided by the triage nurse depending on the patient's code and injected by an emergency doctor.

Settings and conduct

This study will be performed on patients with renal colic in Emergency Hospital of Imam Khomeini Hospital and Golestan Ahvaz in 1397. The study was blind in two ways, the patient and the physician were unaware of the treatment.

Participants/Inclusion and exclusion criteria

In this study, a number of patients suffering from kidney stone pain referring to Imam Khomeini and Golestan Hospitals of Ahwaz with flank pain that radiates to the genitalia, nausea, vomiting, urinary tract and tenderness in the costovertebral region will include in the study. However, opioid-dependent patients received analgesic pain up to 6 hours before entering the ED, refusal of the renal colic due to the presence of stones, history of chronic kidney disease, history of the chronic liver disease, history of ketamine or fentanyl allergies will be excluded from the study

Intervention groups

The first group received intranasal fentanyl 1mg / kg and distilled water IV and the second group received 1mg / kg body weight of 50mg / ml solution of Ketamine I.V and intra-nasal distilled water. Then, the efficacy of the treatment is compared in both groups

Main outcome variables

Pain severity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180523039805N1**
Registration date: **2018-09-01, 1397/06/10**
Registration timing: **prospective**

Last update: **2018-09-01, 1397/06/10**

Update count: **0**

Registration date

2018-09-01, 1397/06/10

Registrant information

Name

Seyed alireza Sabouhi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2654 4524

Email address

sabouhi.a@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2019-04-21, 1398/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the therapeutic effects of intranasal ketamine and intravenous fentanyl in the treatment of patients with renal colic

Public title

Compare the efficacy of intranasal ketamine and intravenous fentanyl in patients with kidney pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who suffer from kidney pain caused by kidney stones Patients who have symptoms of nausea, vomiting and Urinary irritation

Exclusion criteria:

Opioid dependence History of mental illness Changes in consciousness Get an analgesic for 6 hours before entering the emergency department Unconfirmed renal colic due to the presence of stones History of seizure History of chronic kidney disease Glaucoma Patients under the age of 15 and over 65 years History of chronic liver disease Inability to speak History of allergy to ketamine or fentanyl History of chronic respiratory illness Abnormal brain

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **122**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomize in two groups with eight unit Permutational blocks. Permuted block randomization is a way to randomly allocate a participant to a treatment group, while maintaining a balance across treatment groups. Each "block" has a specified number of randomly ordered treatment assignments. In this case, We will generate the blocks containing 8 number

Blinding (investigator's opinion)

Double blinded

Blinding description

The patients know they are participating in a study that is aimed to compare the efficacy and side effects of ketamine and Fentanyl in the reduction of renal colic pain but they are not informed that they receive Ketamine or Fentanyl. 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. Intranasal or Intravenous distilled water will be used as a placebo

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical commite of Jundishapur University of Ahvaz

Street address

Golestan

City

Ahvaz

Province

Khuzestan

Postal code

6435134551

Approval date

2018-04-21, 1397/02/01

Ethics committee reference number

IR.AJUMS.REC.1397.019

Health conditions studied

1

Description of health condition studied

renal colic

ICD-10 code

N20.0

ICD-10 code description

Calculus of kidney

Primary outcomes

1

Description

Renal colic severity

Timepoint

before intervention and 5, 15 , 30 minutes after intervention

Method of measurement

VAS questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The group will receive 1 Mg/Kg Ketamine I.V and 1Mg/kg intranasal distilled water

Category

Treatment - Drugs

2

Description

Intervention group: The group will receive 1Mg / kg fentanyl intranasal and 1 mg/kg intravenous distilled

water
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Ahvaz Imam Khomeini Hospital
Full name of responsible person
Seyed Alireza Sabouhi
Street address
Golestan
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for Research, Ahvaz Jundishapur
University of Medical Sciences, Ahvaz, Iran
Full name of responsible person
Mohammad Badvi
Street address
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Khuzestan
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6455134358
Phone
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Email
Sabouhi.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
Vice Chancellor for Research, Ahvaz Jundishapur
University of Medical Sciences, Ahvaz, Iran
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
Seyed alireza Sabouhi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Emergency Medicine
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is not a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available