

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

Compression of intranasal ketamine, intranasal fentanyl adjunct to intravenous ketorolac on renal colic pain relief: A Randomized Clinical Trial

Protocol summary

Study aim

Compression of intranasal ketamine, intranasal fentanyl adjunct to intravenous ketorolac on renal colic pain relief

Design

Randomized control trial, randomization by random schedule, double blinded, 3 parallel groups (40 patients in each group)

Settings and conduct

120 patients admitted to the emergency department of Shahid Sadoughi and Shahid Rahneemoon hospitals in Yazd based on inclusion and exclusion criteria will be randomly allocated into three groups: Group A: 1 milligram per kilogram intranasal ketamine and 30 milligrams intravenous ketorolac, group B: 1 microgram per kilogram intranasal fentanyl and 30 milligrams intravenous ketorolac and for group C nasal placebo spray and 30 milligrams intravenous ketorolac will be prescribed and the severity of pain (by Visual Analogue Scale score) and complications of drugs will be determined in 0, 5, 10, 15, 30 and 60 minutes. The drugs will be prescribed by a triage nurse and none of patients nor physician won't know which drug was to be prescribed.

Participants/Inclusion and exclusion criteria

All 15 to 64 years old patients suspected for renal colic and urolithiasis based on urine analysis and imaging (ultrasonography or CT scan), history and physical examination; Pregnancy, fever, hemodynamic instability, allergy or addiction to prescribed medication, nasal congestion, history of renal, cardiac or hepatic failure, brain tumor, glaucoma, peptic ulcer and psychosis, consumption of analgesic drugs in 4 last hours, VAS score below 5

Intervention groups

Group A: 1 milligram per kilogram intranasal ketamine (maximum 50 milligrams) and 30 milligrams intravenous ketorolac Group B: 1 microgram per kilogram intranasal

fentanyl (maximum 50 micrograms) and 30 milligrams intravenous ketorolac Group C: nasal placebo spray and 30 milligrams intravenous ketorolac

Main outcome variables

Severity of pain measured by Visual Analogue Scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201028049179N1**

Registration date: **2020-11-02, 1399/08/12**

Registration timing: **registered_while_recruiting**

Last update: **2020-11-02, 1399/08/12**

Update count: **0**

Registration date

2020-11-02, 1399/08/12

Registrant information

Name

Fateme Sadat Zebhi Ashkezari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3272 2673

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-29, 1399/07/08

Expected recruitment end date

2020-12-28, 1399/10/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compression of intranasal ketamine, intranasal fentanyl adjunct to intravenous ketorolac on renal colic pain relief: A Randomized Clinical Trial

Public title

Compression of intranasal ketamine, intranasal fentanyl adjunct to intravenous ketorolac on renal colic pain relief

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

All patients suspected for renal colic and urolithiasis based on urine analysis and imaging (ultrasonography or CT scan), history and physical examination. Age between 15 to 64

Exclusion criteria:

Pregnancy Addiction to opioids and psychedelics Allergy to fentanyl, ketamine and ketorolac Fever (body temperature more than 38°C) and suspicion of pyelonephritis Systolic blood pressure above 180 mm Hg or below 90 mm Hg, respiratory rate below 12 per minute and heart rate above 140 or below 60 History of liver, renal or cardiovascular disease, active peptic ulcer, brain tumors, glaucoma and psychosis Consumption of analgesic drugs in the last 4 hours VAS score below 5 Congestion of both nostrils

Age

From **15 years** old to **64 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Individual simple randomization Based on a random sequence of numbers from Random.org, a table will be prepared, with the first forty consecutive numbers in Group A, the next forty consecutive numbers in Group B, and the final forty consecutive numbers in Group C. These numbers will be assigned to each patient in order of admission.

Blinding (investigator's opinion)

Double blinded

Blinding description

The drug will be prescribed by a triage nurse, according

to random number generator and none of the patients nor physician won't know which drug was to be prescribed.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Research Ethics Committee of School of Medicine- Shahid Sadoughi University of Medical Sciences

Street address

Central building of Shahid Sadoughi University of Medical Sciences, Bahonar square, Yazd

City

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Province

Yazd

Postal code

89416978477

Approval date

2020-07-11, 1399/04/21

Ethics committee reference number

IR.SSU.MEDICINE.REC.1399.081

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**

Severity of renal colic pain according to Visual Analogue Scale score

Timepoint

Initiation of study and 5, 10, 15, 30 and 60 minutes after prescription medication

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: first intervention group: Group A: 1 milligram per kilogram intranasal ketamine (maximum 50 milligrams, 25 milligrams in each nostril) and 30 milligrams intravenous ketorolac by a 2 cc syringe in 15 seconds

Category

Treatment - Drugs

2

Description

Intervention group: second intervention group: Group B: 1 microgram per kilogram intranasal fentanyl (maximum 50 micrograms, 25 micrograms in each nostril) and 30 milligrams intravenous ketorolac injected by a 2 cc syringe in 15 seconds

Category

Treatment - Drugs

3

Description

Control group: Group C: nasal placebo spray and 30 milligrams intravenous ketorolac injected by a 2 cc syringe in 15 seconds

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sadoughi hospital

Full name of responsible person

Soheila Azimi Aabarghouei

Street address

Emergency ward, Ebne Sina Blvd, Yazd

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Web page address

2

Recruitment center

Name of recruitment center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Fateme Sadat Zebhi Ashkezari

Position

Medical student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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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