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 Rahnemoon 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)

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+98 35 3272 2673

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zebhiashkezari@gmail.com

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
Yazd
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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2

Recruitment center
Name of recruitment center
Shahid Rahnemoon hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Central building of Shahid Sadoughi University of Medical Sciences, Bahonar square, Yazd
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Email
info@ssu.ac.ir
Web page address
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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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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