Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

Comparison of intranasal desmopressin and intranasal ketamine in pain control in patients with renal colic

Protocol summary

Study aim

The aim of this study was to compare the efficacy, speed of action and side effects between administration of desmopressin and ketamine spray in analgesia of renal colic patients.

Design

Double-blind, randomized parallel-group clinical trial

Settings and conduct

After obtaining the code of ethics from the ethics committee of Isfahan University of Medical Sciences and obtaining written consent from 135 eligible patients, they are divided into three groups of 45 cases using a computer-generated random number table with 4 blocks. In the first group desmopressin, in the second group intranasal ketamine and in the third group placebo are administered. After receiving the initial analgesic, the pain score is assessed by VAS at 10, 30 and 60 minutes. Finally, the vital signs of patients including heart rate, respiration rate, oxygen saturation and systolic and diastolic blood pressure are measured and recorded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Adult patients with renal colic or typical renal colic pain referred to the emergency department with severe pain (VAS> 5) and age less than 65 years. Exclusion criteria: hypertension and patients with heart, liver and Kidney, rhinitis, drug addicts, pregnant patients, patients treated with anticoagulants, patients with decreased level of consciousness. Also, patients who were diagnosed with other causes such as appendicitis. Hypersensitivity to desmopressin, ketamine and morphine and history of analgesic use within 6 hours before the procedure

Intervention groups

Patients aged 18 to 65 years who are diagnosed with renal colic need analgesic treatment.Intervention group 1: nasal desmopressin and ketorolac. Intervention group 2: ketamine intranasel and ketorolac. Control group: placebo and ketorolac

Main outcome variables

The severity of pain is measured based on the VAS scale.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180129038549N12**
Registration date: **2021-06-21, 1400/03/31**
Registration timing: **prospective**

Last update: **2021-06-21, 1400/03/31**
Update count: **0**

Registration date

2021-06-21, 1400/03/31

Registrant information

Name

Farhad Heydari

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-22, 1400/04/01

Expected recruitment end date

2021-12-22, 1400/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of intranasal desmopressin and intranasal ketamine in pain control in patients with renal colic

Public title
Desmopressin in the treatment of renal colic
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Adult patients referred to the emergency department Known patient with renal colic or typical renal colic pain Severe pain (VAS> 5) Age less than 65 years Informed consent to participate in the study
Exclusion criteria:
History of hypertension Patients with heart failure, liver and kidney failure History of analgesic use within 6 hours before the admission History of drug addiction Pregnant patients Patients with decreased level of consciousness Patients with unstable vital signs Hypersensitivity to desmopressin, ketamine and morphine
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **135**
Randomization (investigator's opinion)
Randomized
Randomization description
After the arrival of the patients to the emergency department, they are divided into 3 groups by a computer-generated random number table with 6 blocks. The selected subjects will be divided into each study group in a randomized block method using 6 rows of four blocks (ABCABC-BACBAC-ACBBCA-BCAACB-AABBCC-CCBBAA). Desmopressin group (A), Ketamine group (B) and placebo group (c). Then, from the created blocks, enough blocks are randomly selected to reach the required sample size. Select the number of blocks from the table of random numbers and based on these numbers, the sequence of blocks in each group will be determined. All this will be done with software called Sealed Envelope.
Blinding (investigator's opinion)
Double blinded
Blinding description
First, ketamine and placebo (distilled water) sprays are packaged similar to desmopressin spray and then numbered and given to the triage nurse. The nurse, doctor and patient do not know the contents of the ointment.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Science
Street address
Isfahan University of Medical Science, Hezarjrib Street, Isfahan City
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2021-05-12, 1400/02/22
Ethics committee reference number
IR.MUI.MED.REC.1400.191

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
The severity of pain
Timepoint
In 10, 30 and 60 minutes after receiving the drug
Method of measurement
Visual Analogue Scale

Secondary outcomes

1

Description
Side effects

Timepoint
every 10 minutes
Method of measurement
Physical exam

2

Description
Vital signs (blood oxygen saturation level, pulse rate and respiratory rate per minute)
Timepoint
Every 10 minutes
Method of measurement
Physical exam

Intervention groups

1

Description
Intervention group: They will be received nasal desmopressin at a dose of 40 mcg, equivalent to 2 puffs per nose, and ketorolac at a dose of 30 mg / ml. Effective treatment is when the pain is reduced by at least 50% of the initial pain or a score of 3 out of 10 VAS scores. Morphine will be given at a dose of 0.1 mg / kg if the patient's pain does not decrease effectively after 30 minutes of drug administration.
Category
Treatment - Drugs

2

Description
Intervention group: They will be received nasal ketamine at a dose of 1 mg/kg, and ketorolac at a dose of 30 mg / ml. Effective treatment is when the pain is reduced by at least 50% of the initial pain or a score of 3 out of 10 VAS scores. Morphine will be given at a dose of 0.1 mg / kg if the patient's pain does not decrease effectively after 30 minutes of drug administration.
Category
Treatment - Drugs

3

Description
Control group: They will be received nasal placebo, and ketorolac at a dose of 30 mg / ml. Effective treatment is when the pain is reduced by at least 50% of the initial pain or a score of 3 out of 10 VAS scores. Morphine will be given at a dose of 0.1 mg / kg if the patient's pain does not decrease effectively after 30 minutes of drug administration.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra hospital
Full name of responsible person
Farhad Heydari
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2

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Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh haghjooy javanmard
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Isfahan University of Medical Sciences, P.O. Box 319, Hezar-Jerib Ave.
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Email
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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
Esfahan University of Medical Sciences
Proportion provided by this source
10
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
Esfahan University of Medical Sciences
Full name of responsible person
Farhad Heydari
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Emergency Medicine
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
All of data after coding
When the data will become available and for how long
Accessibility after 2022
To whom data/document is available
Everyone
Under which criteria data/document could be used
For seemingly studies data released to academic chairman's

From where data/document is obtainable

Isfahan University of Medical Sciences

What processes are involved for a request to access data/document

Emailing to farhad_heidari@med.mui.ac.ir

Comments