Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

Comparison the effect of intranasal Ketamin versus intravenous Morphine on pain in patients with renal colic referring to the Emergency department of Khatam-ol-anbia hospital in Zahedan in 2018

Protocol summary

Study aim

1. Determine the relative mean patients with renal colic in separate groups 2. Determination of the mean pain score at 0, 30 and 60 minutes, based on the VAS scale in the two groups of ketamine and morphine 3. Determination and comparison of mean pain at 0, 5, 30 and 60 minutes, based on the VAS scale in two groups of ketamine and morphine in terms of age 4. Determine and compare the pain at 0, 5, 30, and 60 minutes, based on the VAS scale in the two groups of ketamine and morphine in terms of gender

Design

In this research, 100 patients with renal colic who have entering criteria referred to emergency department of Khatam-ol-Anbia Hospital in two intervention groups are included. Their allocation to the two groups of ketamine and morphine is based on random blocking. Phase 3 of the trial is used in this study.

Settings and conduct

Renal colic is the cause of a significant proportion of patients in hospital emergency and clinic emergency that is associated with severe pain. Usually, the nature of these pains despite being transient, it is very debilitating and intolerable to the patient. after initial diagnostic evaluations, since most urinary stones recover with anticipated treatment, the most important treatment priority In the acute stage, is to relieve pain. In this research, 100 patients with renal colic who have entering criteria referred to emergency department of Khatam-ol-Anbia Hospital in two intervention groups are included. Their allocation to the two groups of ketamine and morphine is based on random blocking. Phase 3 of the trial is used in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Uncontrollable pain due to renal colic that causes prescribing other painkillers; Not suffering from other underlying disease(Renal- cardiac -liver-DM); age 20-50; No addiction; Not sensitivity to Morphine and ketamine and the lack of pharmaceutical contraindication Exclusion criteria: Pregnant and lactating women; Having blood pressure Dbp <90 and Sbp >80; Nasal congestion; respiratory distress; History of seizure ; History of GLAUCOMA; History of drug abuse

Intervention groups

1. Ketamine group: Ketamine will be injected 1 mg per kg into this group patients. 2. Morphine group: Morphine will be injected 0.1mg per kg into this group patients..

Main outcome variables

pain: will be measured by the vas scale.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171229038132N1**
Registration date: **2018-02-06, 1396/11/17**
Registration timing: **registered_while_recruiting**

Last update: **2018-02-06, 1396/11/17**
Update count: **0**

Registration date

2018-02-06, 1396/11/17

Registrant information

Name

Mohammad mehdi Saghab torbati

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3322 0501

Email address

m.torbati@zaums.ac.ir

Recruitment status

Recruitment complete
Funding source

Expected recruitment start date
2018-01-29, 1396/11/09
Expected recruitment end date
2018-07-31, 1397/05/09
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison the effect of intranasal Ketamin versus intravenous Morphine on pain in patients with renal colic referring to the Emergency department of Khatam-ol-anbia hospital in Zahedan in 2018

Public title
Comparison the effect of drugs in patients with renal colic
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Uncontrollable pain due to renal colic that needing other prescription painkiller drugs Not suffering from other underlying disease (Renal, Cardiac, Liver, DM) Age 20-50 No drug addiction Not sensitivity to Morphine and Ketamine and the lack of pharmaceutical contraindication
Exclusion criteria:
Pregnant and lactating women Having blood pressure Dbp <90 and Sbp >80 Nasal congestion Respiratory distress History of Seizure History of Glaucoma History of drug abuse
Age
From **20 years** old to **50 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
N/A
Randomization description
After entering randomly blocked patients, patients are divided into two groups that will be matched for pain before medication and age and sex.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Zahedan University of Medical Sciences
Street address
Zahedan University of Medical Sciences, Dr hesabi sq.
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Approval date
2017-12-21, 1396/09/30
Ethics committee reference number
IR. ZAUMS. REC.1396. 271

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 pain that will be measured by the Vas scale
Timepoint
The pain measurement will be measured at 0, 5, 15, 30 and 60 minutes after medication administration
Method of measurement
The Vas pain scale that has a score of 0 to 10

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group1: In this group, Ketamine will be given as nasal for pain.

Category
Treatment - Drugs

2

Description
Intervention group2: In this group, Morphin will be injected for pain
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Khatam ol-Anbia Hospital in Zahedan City
Full name of responsible person
Aziz Allah Jahantigh
Street address
Khatam ol anbia hospital, Jame jam Boulevard
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9815733169
Phone
+98 54 3322 0501
Email
aa_jahantigh@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Noormohammad Bakhshani
Street address
Zahedan University of Medical Sciences, Dr hesabi sq.
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bakhshani@zaums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zahedan 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
Zahedan University of Medical Sciences
Full name of responsible person
Mohammad Mehdi Saghab Torbati
Position
Resident of Medicine
Latest degree
Medical doctor
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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Only part of the information, such as the main outcome information, can be shared.

When the data will become available and for how long
Start the access period 6 months after printing the results

To whom data/document is available
Researchers working in academia

Under which criteria data/document could be used
Any use of the data will be subject to the permission of the project owners.

From where data/document is obtainable
Zahedan University of Medical Sciences

What processes are involved for a request to access data/document
Documentation will be available after confirmation of the administrative request for the use of the project.

Comments