

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 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.

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Phone

+98 54 3329 5715

Email

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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Zahedan University of Medical Sciences, Dr hesabi sq.

City

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Province

Sistan-va-Balouchestan

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9816743463

Phone

+98 54 3329 5715

Email

m.torbati@zaums.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Zahedan University of Medical Sciences

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Person responsible for updating data

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

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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