

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Evaluation of Ketamine effect against morphine effect on Renal colic Pain management

Protocol summary

Study aim

This study is designed to evaluation an alternative relief regime for patients with renal colic.

Design

Controlled clinical trial with parallel group, single-blind randomized, Phase 3 on 80 patients. The rand function of the Excel software is used for randomization.

Settings and conduct

Randomized single-blind randomized clinical trial (patients blinded to the patient's lack of knowledge of the drug), patients admitted to the emergency department of Kowsar and Tohid hospitals with acute renal colic attack, with informed consent of the patients, randomly (using the method of random blocks) are divided into two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Renal colic Exclusion criteria: Drug hypersensitivity People with stroke or high blood pressure Eye injuries Increased cerebrospinal fluid pressure Increased intraocular pressure Psychiatric disorders such as schizophrenia Toxic thyroid Unwillingness to enter the study

Intervention groups

The first intervention group received 0.1 mg / kg morphine intravenously and 5 cc normal saline as placebo BY nasal spry, the second intervention group 0.15 mg / kg oral ketamine by nasal spry plus 5 cc normal saline as placebo

Main outcome variables

Pain grade caused by kidney stones

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141208020249N7**

Registration date: **2020-09-27, 1399/07/06**

Registration timing: **retrospective**

Last update: **2020-09-27, 1399/07/06**

Update count: **0**

Registration date

2020-09-27, 1399/07/06

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-20, 1398/12/01

Expected recruitment end date

2020-09-21, 1399/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Ketamine effect against morphine effect on Renal colic Pain management

Public title

The effect of ketamine on renal colic

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Flank colic with kidney stone diagnosis

Exclusion criteria:

Drug hypersensitivity People with stroke or high blood pressure Eye injuries Increased cerebrospinal fluid pressure Increased interocular pressure Psychiatric disorders such as schizophrenia Toxic thyroid Unwillingness to enter the study

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: 80

Randomization (investigator's opinion)

Randomized

Randomization description

Excel software rand function is used for randomization. To do this, we create a column of numbers from one to 80 using the command =RAND () * (0-0-80) random numbers. The columns of even numbers are in the case group and the odd numbers are in the control group, respectively.

Blinding (investigator's opinion)

Single blinded

Blinding description

The injected drug is given to patients prepared in the syringe and inhaled drug is given to patients prepared in the sprayer with code, and only the researcher will be aware of its contents.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Kurdistan University of Medical Sciences

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Management of Medical Researches and Information, Kurdistan University of Medical Sciences, Pasdaran Blvd, Sanandaj, Kurdistan, Iran POB 6617713446

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Approval date

2020-01-28, 1398/11/08

Ethics committee reference number

IR.MUK.REC.1398.276

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**

Renal colic score

Timepoint

Minutes 0, 10, 15, 30, 60

Method of measurement

Visual analog scale

Secondary outcomes

empty

Intervention groups**1****Description**

Control group: 0.1 mg / kg intravenous morphine and 5 cc normal saline nasal spray as placebo

Category

Treatment - Drugs

2**Description**

Intervention group: 0.15 mg / kg nasal spray ketamine plus 5 cc normal saline as placebo

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Tohid Hospital

Full name of responsible person

Kourosh Akhbari

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Recruitment center

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Sponsors / Funding sources

1

Sponsor

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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
Sanandaj 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
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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

All data is from the proposal, raw data and project reports

When the data will become available and for how long

Data is available from the legal system six months after publication for two years

To whom data/document is available

All persons will be able to access the Kurdistan University of Medical Sciences's request to the Kurdistan University of Medical Sciences.

Under which criteria data/document could be used

For legal issues and the need to use data in future studies

From where data/document is obtainable

Kourosh Akhbari, Alireza Honarmand, Behzad Khalafi

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

After submitting a request to the Kurdistan Research and Technology Dept. of Science and Technology, a call for submission is given.

Comments