Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
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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

Street address
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 spry as placebo

Category
Treatment - Drugs

2

Description
Intervention group: 0.15 mg / kg nasal spry 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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Sponsors / Funding sources

1

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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

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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