Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jun 2026

Comparison of Low dose Ketamin plus Morphine versus Morphine alone in acute pain management of severe renal colic

Protocol summary

Summary

In randomized, double-blind study patient between 18 to 50 years old with nephrolithiasis and severe renal colic be visited to one of the hospitals that are affliated to Tehran University accidently they are divided to two categories. One group with morphine plus placebo (mp) and the other group with morphine plus ketamine (mk) prescribed. The patients have inclusion criteria will be accepted and exclusion criteria will not. All patients were assessed for pain by using VAS chart. One group received Morphine (0.1 mg/kg intravenous) and placebo, and another group received morphine with the same dose and ketamine (0.1 mg/kg/dose intravenous , maximum dose = 0.4 mg/kg).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201109297667N1**
Registration date: **2012-03-14, 1390/12/24**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-03-14, 1390/12/24

Registrant information

Name

Nader Bidi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6652 5327

Email address

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Recruitment status

Recruitment complete

Funding source

Tehran University of medical sciences

Expected recruitment start date

2012-02-26, 1390/12/07

Expected recruitment end date

2012-06-20, 1391/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Low dose Ketamin plus Morphine versus Morphine alone in acute pain management of severe renal colic

Public title

Effect of ketamine and morphine in pain management of renal colic

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Previous nephrolithiasis , age between 18 to 50 years old, severity of pain at least 6 from 10, systolic blood pressure >= 90 mmHg, heart rate = 60-120/m, respiratory rate = 8-22/m, o2sat >= 90%, no addiction to opiate or psychiatric drugs, no use analgesic drugs or opioid before recording the data, no history of chronic liver disease or kidney or respiratory disease, no history of coagulopathy or blood disorders or chronic psychiatric disorder, no use of psychiatric drugs.
Exclusion criteria: The patient who is not interested in study, addiction to opiate or psychiatric drugs, allergy to morphine or ketamine, inability to perception of VAS

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences Ethics Committee

Street address

Hemmat highway,Tehran

City

Tehran

Postal code

Approval date

2012-02-25, 1390/12/06

Ethics committee reference number

2315

Health conditions studied

1

Description of health condition studied

Renal colic

ICD-10 code

N20

ICD-10 code description

Calculus of kidney and ureter

Primary outcomes

1

Description

Severity of pain

Timepoint

Before prescription the medication, 10, 30, 60, 90 and 120 minutes after medication

Method of measurement

VAS (visual analog scale)

Secondary outcomes

1

Description

nausea

Timepoint

Before prescription the medication, 10, 30, 60, 90 and 120 minutes after medication

Method of measurement

Questionnaire

2

Description

agitation

Timepoint

Before prescription the medication, 10, 30, 60, 90 and 120 minutes after medication

Method of measurement

Questionnaire

3

Description

diplopia

Timepoint

Before prescription the medication, 10, 30, 60, 90 and 120 minutes after medication

Method of measurement

Questionnaire

4

Description

hallucination

Timepoint

Before prescription the medication, 10, 30, 60, 90 and 120 minutes after medication

Method of measurement

Questionnaire

Intervention groups

1

Description

One group received morphine 0.1 mg/kg intravenous and ketamine (0.1 mg/kg/dose intravenous , maximum dose = 0.4 mg/kg),

Category

Treatment - Drugs

2

Description

another group received Morphine (0.1 mg/kg

intravenous) and placebo

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emergency department of Hazrat Rasool hospital

Full name of responsible person

Dr. Bdi nader

Street address

Sattarkhan St., Niaiesh

City

Tehran

2

Recruitment center

Name of recruitment center

Emergency department of Sina hospital

Full name of responsible person

Dr. Bidi nader

Street address

Imam Khomeini Sq, Hasan abad

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences-Deputy for research affairs

Full name of responsible person

Dr akhondzadeh shahin

Street address

Tehran-keshavarz St-porsina St-tehran university-Deputy for research affairs

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran University of Medical Sciences-Deputy for research affairs

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Bidi nader

Position

MD

Other areas of specialty/work

Street address

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Person responsible for scientific inquiries

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty