

# 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 affiliated to Tehran University accidentally 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

n-bidi@razi.tums.ac.ir

##### 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  $\geq 90$  mmHg, heart rate = 60-120/m, respiratory rate = 8-22/m, o<sub>2</sub>sat  $\geq 90\%$ , 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**

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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*