

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

A Comparison, between the analgesic effects of intravenous morphine sulfate with ketamine regimen, and intravenous morphine sulfate regimen solely, in management of the acute pain in renal colic patients who admitted to the emergency department of Imam Khomeini hospital of Sari in year 1394

Protocol summary

Summary

This double-blind clinical trial will be done to determine the effect of the combination of morphine and ketamine, in comparison with morphine alone in patients with acute renal colic pain. The inclusion criteria are VAS pain score between 7 and 10. Exclusion criteria a history of opium dependency and taking analgesics during last 6 ours prior to the visit. The study population will be included 200 patients with acute renal colic pain referred to Imam Khomeini Hospital. After getting informed consent from people, participants will be divided into two groups. In the first group, intravenous morphine and ketamine and the second group morphine and normal saline will be precipitated. The VAS pain score will be assessed zero, 20 and 40 minutes after the injection. The criteria for treatment response will be a pain score less than 4.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015080523517N1**

Registration date: **2017-04-15, 1396/01/26**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-04-15, 1396/01/26

Registrant information

Name

Salman Erfanian Irankar

Name of organization / entity

Mazandaran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences

Expected recruitment start date

2015-09-20, 1394/06/29

Expected recruitment end date

2017-05-22, 1396/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Comparison, between the analgesic effects of intravenous morphine sulfate with ketamine regimen, and intravenous morphine sulfate regimen solely, in management of the acute pain in renal colic patients who admitted to the emergency department of Imam Khomeini hospital of Sari in year 1394

Public title

The effects of intravenous morphine sulfate with ketamine in renal pain.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: All patients with acute renal colic with VAS pain score between 7 and 10. Exclusion criteria: Pregnancy or probable pregnancy; Breast feeding; Contraindications for Morphine usage; History of opium addiction; Taking any analgesics during last 6 hours prior of admission; Peritoneal signs and symptoms in abdominal examination; History of cardiovascular diseases; Psychosis; Refusal of the patients from the participation.

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mazandaran University of Medical Sciences

Street address

Jouybar crossroad

City

Sari

Postal code

Approval date

2017-04-09, 1396/01/20

Ethics committee reference number

IR.MAZUMS.REC.94.1719

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

Pain

Timepoint

Zero, 20 and 40 minute after intervention

Method of measurement

Visual analogue scale

Secondary outcomes

1

Description

Respiratory rate

Timepoint

Zero, 20 and 40 minute after intervention

Method of measurement

Respiratory rate in minute

2

Description

Nausea

Timepoint

Zero, 20 and 40 minute after intervention

Method of measurement

Positive/negative

3

Description

Vomiting

Timepoint

Zero, 20 and 40 minute after intervention

Method of measurement

Positive/negative

4

Description

Vertigo

Timepoint

Zero, 20 and 40 minute after intervention

Method of measurement

Positive/ negative

5

Description

Blood pressure

Timepoint

Zero, 20 and 40 minute after intervention

Method of measurement

mmHg

6

Description

Rash or hives

Timepoint

Zero, 20 and 40 minute after intervention

Method of measurement

Positive/ negative

Intervention groups

1

Description

Morphine sulfate with 0.1 mg / kg the time of intervention and if necessary 0.05 mg / kg in 20 minute after intervention in both control and experimental groups

Category

Treatment - Drugs

2

Description

Ketamine 0.2 mg/kg before the time of intervention in experimental group

Category

Treatment - Drugs

3

Description

Placebo(normal saline) 5 ml at the time of intervention in control group

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital of Sari , emergency department

Full name of responsible person

Salman Erfanian Irankar

Street address

Imam khomeina hospital emergency department

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr Ahmadali Enayati

Street address

Moallem square

City

Sari

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mazandaran University of Medical Sciences

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

Mazandaran University of Medical Sciences

Full name of responsible person

Salman Erfanian Irankar

Position

Resident of emergency medicine

Other areas of specialty/work

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Imam Khomeini hospital

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Person responsible for scientific inquiries

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Full name of responsible person

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Other areas of specialty/work

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Mazandaran university of medical sciences

Full name of responsible person

Salman Erfanian Irankar

Position

Resident of emergency medicine

Other areas of specialty/work**Street address**

Imam Khomeini hospital

City

Sari

Postal code**Phone****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