

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Comparison of analgesic effect of intranasal ketamine and intravenous morphine in patients with renal colic

Protocol summary

Summary

The aim of the study is evaluation of analgesic effect of ketamine in renal colic patients. This is a randomized double blind clinical trial and all patient who come to emergency department with acute renal colic (diagnosed by past history and clinical sign) and signed inform consent form and have not exclusion criteria of the study(unwilling to study participation, drug allergy) , include to the trial. The study population is 25 patients in each group. With block randomization each patients allocated to one of two groups. Group 1, receive 1 mg/kg intranasal ketamine as analgesic and intravenous sodium chloride solution as placebo and group2, receive 0.1 mg/kg intravenous morphine as analgesic and intranasal sodium chloride solution as placebo. At the beginning of study and after 15 and 30 min of intervention we calculate pain level of patients with using of visual analog scale. We use 0.75 mcg/kg fentanyl as rescue analgesic if, 1- persistent pain after 30 min 2- changing in VAS score < 13 mm 3- patients willing

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201412208872N8**

Registration date: **2015-01-18, 1393/10/28**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-01-18, 1393/10/28

Registrant information

Name

Morteza Saeedi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8490 2719

Email address

m_saeedi@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2015-01-04, 1393/10/14

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of analgesic effect of intranasal ketamine and intravenous morphine in patients with renal colic

Public title

analgesic effect of intranasal ketamine in patients with renal colic

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: all patient with high clinical suspicious of renal colic; all patient who come with pain and have clinical or lab data of renal colic. Exclusion criteria: age < 15 years; unwilling to study participation; past history of allergy to morphine or ketamine; pregnancy; history of analgesic drug consumption < 6 hours ago; peritoneal sign; liver; renal or heart failure patients; decrease level of consciousness; mental disability

Age

From **15 years** old
Gender
Both
Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **50**
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

Tehran University of Medical Sciences

Street address

No. 1, North door of Tehran university, Poursina street, Enghelab street

City

Tehran

Postal code

Approval date

2014-11-15, 1393/08/24

Ethics committee reference number

93/130/1997/ص

Health conditions studied

1

Description of health condition studied

urolithiasis

ICD-10 code

N20

ICD-10 code description

Calculus of kidney and ureter

Primary outcomes

1

Description

pain due to urolithiasis

Timepoint

0, 15, 30 min

Method of measurement

Visual analog scale

Secondary outcomes

1

Description

side effects

Timepoint

during discharge

Method of measurement

questionary

2

Description

patients satisfaction

Timepoint

during discharge

Method of measurement

questionary

Intervention groups

1

Description

Group 1: receive 1 mg/kg intranasal ketamin as analgesic and intravenous sodium chloride solution as placebo. We use 0.75mcg/kg fentanyl as rescue analgesic if, 1- persistent pain after 30 min 2- changing in VAS score < 13mm 3- patients willing

Category

Treatment - Drugs

2

Description

group2, receive 0.1 mg/kg intravenous morphine as analgesic and intranasal sodium chloride solution as placebo. We use 0.75mcg/kg fentanyl as rescue analgesic if, 1- persistent pain after 30 min 2- changing in VAS score < 13mm 3- patients willing

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Dr. Alireza Jalali

Street address

Sina Hospital, Hsan Abad Square, Imam Khomeini Street

City

Tehran

2

Recruitment center

Name of recruitment center

Shariati Hospital

Full name of responsible person

Dr. Morteza Saeedi

Street address

Shariati Hospital, North Amirabad Street

City

Tehran

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Shahin Akhondzadeh Basti

Street address

No.1, North door of Tehran university, Poursina street,
Enghelab stree

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

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 Morteza Saeedi

Position

Assistant Professor/ Emergency Medicine Specialist

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

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

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Person responsible for updating data

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Position

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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