Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jun 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

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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
quessionary

2

Description
patients satisfaction

Timepoint
during discharge

Method of measurement
quessionary

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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Shahin Akhondzadeh Basti
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No.1, North door of Tehran university, Poursina street, Enghelab stree
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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
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
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Person responsible for updating data

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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