Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation the therapeutic effects of intravenous Ketamine and intravenous Morphine in the treatment of patients with renal colic

Protocol summary

Study aim
Comparison of the therapeutic effects of intravenous ketamine and intravenous morphine in the treatment of patients with renal colic

Design
The double-blind clinical trial, with parallel groups, randomized. 47 patients In each group, the first group will receive 0.3 mg/kg of intravenous Ketamine and the second group will receive 0.1 mg/kg of intravenous Morphine.

Settings and conduct
The present study will be conducted to compare the analgesia of ketamine with morphine in patients admitted to Imam Khomeini hospital of Ahvaz Jundishapur University of Medical Sciences with renal colic. Patients will be divided into two groups based on a block randomized method. Patients will be blind towards the drugs. Analgesia degree will be registered by the blind researcher.

Participants/Inclusion and exclusion criteria
Patients aged 18 to 65 years with stone-related renal colic (confirmed by imaging) were evaluated, while patients with a history of cardiovascular and hypertension, pregnancy, breastfeeding, history of drug addiction, history of seizure and glaucoma were excluded.

Intervention groups
Patients in the first group will receive 0.3 mg/kg of intravenous Ketamine. In the second group, patients will receive a dose of 0.1 mg/kg of intravenous Morphine.

Main outcome variables
Comparison of analgesia based on VAS criteria in both groups

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180530039917N2**
Registration date: **2019-03-05, 1397/12/14**
Registration timing: **retrospective**

Last update: **2019-03-05, 1397/12/14**
Update count: **0**

Registration date
2019-03-05, 1397/12/14

Registrant information

Name
Payam Ghoraian

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 8670 5503

Email address
ghoraian.p@ajums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-04-09, 1397/01/20

Expected recruitment end date
2019-01-21, 1397/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation the therapeutic effects of intravenous Ketamine and intravenous Morphine in the treatment of patients with renal colic

Public title

Comparison of Ketamine and Morphine in patients with renal colic

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

VAS more than 5 Patients with renal colic due to stones (confirmed by imaging)

Exclusion criteria:

History of cardiovascular disease and hypertension Pregnancy Breastfeeding Drug addiction History of seizure Glaucoma

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

4

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **136**

Actual sample size reached: **136**

Randomization (investigator's opinion)

Randomized

Randomization description

The block randomization method (with a block size of four) will be used, and a person unaware of the study objectives will seal the obtained codes in opaque envelopes and then the envelopes will be given to one of the researchers who has no role in the treatment or evaluation. Afterward, the researcher will provide syringes containing the solution base on the confidential codes and will give it to the physician to inject

Blinding (investigator's opinion)

Double blinded

Blinding description

Numbered drugs will be injected muscularly by the medical assistant. The analgesia degree based on the VAS method was registered by a blinded emergency resident.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical commite of Jundishapur University of Ahvaz

Street address

Golestan

City

Ahvaz

Province

Khouzestan

Postal code

6435134551

Approval date

2018-03-03, 1396/12/12

Ethics committee reference number

IR.AJUMS.REC.1396.1035

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 level

Timepoint

Before the intervention, 5, 10, 20, 30 and 60 minutes after the intervention

Method of measurement

Visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: A single dose of 0.3 mg/kg Intravenous Ketamine

Category

Treatment - Drugs

2

Description

Intervention group: A single dose of 0.1 mg/kg Intravenous Morphine

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Ahvaz Imam Khomeini Hospital

Full name of responsible person
Reza Nazi

Street address
Golestan street

City
Ahvaz

Province
Khouzestan

Postal code
56143661

Phone
+98 61 2267 4822

Email
ali.khossravi70@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Deputy of Research and Technology of Ahvaz Jundishapur University of Medical Sciences

Street address
Golestan

City
Ahvaz

Province
Khouzestan

Postal code
6455134358

Phone
+98 61 8876 1241

Email
srnaji@gmail.com

Grant name

Grant code / Reference number

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

Title of funding source
Ahvaz University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Reza Naji

Position
Resident

Latest degree
Specialist

Other areas of specialty/work
Emergency Medicine

Street address
Golestan

City
Ahvaz

Province
Khouzestan

Postal code
6455134358

Phone
+98 21 8670 5503

Fax

Email
srnaji@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Reza Naji

Position
Resident

Latest degree
Specialist

Other areas of specialty/work
Emergency Medicine

Street address
Golestan

City
Ahvaz

Province
Khouzestan

Postal code
6455134358

Phone
+98 21 8670 5503

Fax

Email
srnaji@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Reza Naji

Position
Resident
Latest degree
Specialist
Other areas of specialty/work
Emergency Medicine
Street address
Golestan
City
Ahvaz
Province
Khouzestan
Postal code
6455134358
Phone
+98 21 8670 5503
Fax
Email
srnaji@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available