

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Intra-nasal Ketamine Vs. intravenous morphine in renal colic pain control in emergency patients

Protocol summary

Study aim

To evaluation of intra-nasal ketamine versus intravenous morphine in renal colic pain control in emergency patients

Design

In a phase 3, parallel group, double blind, randomized controlled trial with a simple, individual randomization by using www.randomization.com website; patients older than 18 years old and a complaint of renal colic will be studied in intranasal ketamine or intravenous morphine groups. Each group will have 100 participants.

Settings and conduct

Patients who admitted with renal colic in emergency department of Imam Reza hospital, Tabriz, Iran, will receive treatment by application of study protocol. The participants will be blinded to their treatment group and a placebo will be used. Pain will be scored by using visualize analogue scale. Data will be analyzed by a data analyzer who will be blinded to treatment groups.

Participants/Inclusion and exclusion criteria

Patients older than 18 year old and with a complaint of renal colic will be included in this study and patients younger than 18 year old, patients with a history of allergy to ether ketamine or morphine or patients who received analgesic prior to emergency admission will be excluded.

Intervention groups

Intervention group will receive 1 Mg/Kg of ketamine as nasal spray and 1 CC intravenous normal saline as placebo. Control group will receive 0.1 Mg/Kg of intravenous morphine and four saline puffs of saline nasal spray as placebo.

Main outcome variables

Pain score 15, 30 and 60 minutes after drug administration.

General information

Reason for update

Acronym

INKmor

IRCT registration information

IRCT registration number: **IRCT20121010011067N4**

Registration date: **2019-05-18, 1398/02/28**

Registration timing: **registered_while_recruiting**

Last update: **2019-05-18, 1398/02/28**

Update count: **0**

Registration date

2019-05-18, 1398/02/28

Registrant information

Name

Mahboub Pouraghaei

Name of organization / entity

Tabriz University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 41 1335 2078

Email address

pouraghaeim@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-15, 1398/02/25

Expected recruitment end date

2019-06-15, 1398/03/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Intra-nasal Ketamine Vs. intravenous morphine in renal

colic pain control in emergency patients

Public title

Intra-nasal Ketamine Vs. intravenous morphine in renal colic pain control in emergency patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

More than 18 year old Patients with acute renal colic pain

Exclusion criteria:

Sensitivity to either ketamine or morphine Recent analgesic use before admission

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

simple, individual randomization by using www.randomization.com website.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants and data analyser will be blinded about the treatment method in each treatment group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of medical sciences

Street address

Research Vice chancellor of Tabriz University of Medical Sciences ,Tabriz University of Medical Sciences, Daneshgah Street, Tabriz-51664, I.R IRAN

City

Tabriz

Province

East Azarbaijan

Postal code

5166614776

Approval date

2019-04-08, 1398/01/19

Ethics committee reference number

IR.TBZMED.REC.1398.006

Health conditions studied

1

Description of health condition studied

unspecified renal colic

ICD-10 code

N23

ICD-10 code description

Unspecified renal colic

Primary outcomes

1

Description

Pain control

Timepoint

0, 15, 30 and 60 minutes after intervention

Method of measurement

Visual analog scale for pain

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: One Mg/Kg Ketamine (Rotexmedica pharmaceutical co, Germany) will be administrated intranasally by a nasal spray. One CC on normal saline will injected intravenously as placebo.

Category

Treatment - Drugs

2

Description

Control group: intravenous morphine 0.1 Mg/Kg (Darupakhsh pharmaceutical co. Iran) will be administrated. Four puffs of intranasal saline spay will be used as placebo.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza hospital

Full name of responsible person

Mahboub Pouraghaei

Street address

Emergency Medicine Department, Tabriz University of Medical Sciences, Daneshgah Street, Tabriz-51664, I.R IRAN

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tbzemrt2014@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Abolghasem jouyban

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Mahboub Pouraghaei

Position

associate professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

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Contact

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All collected de-identified IPD.

When the data will become available and for how long

Data will be available in September 2020.

To whom data/document is available

All interested researchers may have access to data.

Under which criteria data/document could be used

Data will be available for use in researches. researchers can ask for data by email and they will receive data in two weeks.

From where data/document is obtainable

pouraghaeim@tbzmed.ac.ir

What processes are involved for a request to access data/document

By sending email to pouraghaeim@tbzmed.ac.ir they can receive data in two weeks

Comments