

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Comparison of the analgesic effect of nebulized Ketamine versus intravenous Ketorolac in reducing pain of patients with renal colic who refer to emergency department

Protocol summary

Study aim

Comparison of analgesic effect of nebulized Ketamine vs IV Ketorolac in reducing pain of patients with renal colic.

Design

Phase 3, randomized, triple-blind, controlled clinical trial with parallel group design of 108 patients.

Settings and conduct

Therapeutic trial in the emergency department of Imam Hossein hospital in Shahroud as a triple-blind (patient, responsible for outcome assessment and statistical analyzer). Assign the code to each of the treatment groups that the nurse is aware of. Patients with renal colic with inclusion criteria are randomly admitted to the intervention or control group. For the intervention group, nebulization 0.5 mg per kg of Ketamine + injection of 1 cc of normal saline and for the control group injection of 1 mg/kg of Ketorolac + nebulization 0.5 cc/kg of distilled water is prescribed. If the pain is not controlled after 2 hours, 0.1 mg/kg of Morphine is injected. The patient's pain is measured according to the NRS and side effects before the study, 5, 15, 30 and 60 minutes after the study. Measuring patient satisfaction at the end of the study.

Participants/Inclusion and exclusion criteria

Inclusion: between 20 to 70 years old, Pain in one side flank. Exclusion: Unstable (SBP<90, HR>100 or HR<60, fever), pregnant, has one kidney, acute abdominal signs (tenderness, guarding, rebound tenderness), hasn't informed consent, history of addiction, history of take analgesic during the previous 6 hours.

Intervention groups

Intervention group: The nurse nebulizes 0.5mg/kg Ketamine and injects 1cc normal saline for each patient. Control group: The nurse injects 1mg/kg of Ketorolac and 0.5cc/kg of distilled water is nebulizes for each patient.

Main outcome variables

Score of renal colic pain in numeric rating scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220201053906N1**

Registration date: **2022-06-05, 1401/03/15**

Registration timing: **registered_while_recruiting**

Last update: **2022-06-05, 1401/03/15**

Update count: **0**

Registration date

2022-06-05, 1401/03/15

Registrant information

Name

Hossein Amiri largani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-22, 1401/03/01

Expected recruitment end date

2022-11-22, 1401/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the analgesic effect of nebulized Ketamine versus intravenous Ketorolac in reducing pain of patients with renal colic who refer to emergency department

Public title

Evaluation of the effect of Ketamine by nebulizer in reducing pain caused by renal colic.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients 20-70 years old With acute pain in one side flank Has informed consent

Exclusion criteria:

Unstable patients (SBP<90, HR>100 or HR<60, fever) Pregnant or Suspicion of pregnancy Single kidney Hasn't informed consent or unable to have informed consent Want to discharge before ending the study(2 hours after starting the study) History of addiction History of take analgesic at least 6 hours Symptom or sign of acute abdominal (tenderness, guarding, rebound) Need Rescue dose before ending of the study

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **108**

Randomization (investigator's opinion)

Randomized

Randomization description

Patient will be randomly divided into 2 groups of 54, using random allocation software. Treatments will start randomly from the first patient who has inclusion criteria. First, the numbers 1 to 108 will be written on 108 envelopes. There is a sheet containing the code of each patient's treatment in each envelope, which is defined by the random allocation software that determines the treatment of each patient. Every patient with inclusion criteria will be allocated an envelope.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is double-blinded. To blind the patient, the pain assessor and statistical analyzer a code will be allocated for each patient. Just emergency medicine specialist and nurse know the meaning of the cods. To make the patient blind, Ketorolac syringe and a placebo nebulizer or Ketamine nebulizer and a placebo syringe will be prepared. After collecting the data, the data will be entered into SPSS using random allocation software codes and will be provided to the statistical analyzer for analysis. Pain is a mental variable, therefore, making the

pain assessor blind is important. So, the pain assessor who assesses the intensity of pain doesn't know the codes of each treatment, just knows the treatment code of each patient.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahroud University of Medical Sciences

Street address

No. 2, Sixth Alley, Shahid Rajaei Ave.,

City

Shahroud

Province

Semnan

Postal code

3616675189

Approval date

2022-01-28, 1400/11/08

Ethics committee reference number

IR.SHMU.REC.1400.235

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

Score of renal colic pain in NRS

Timepoint

Before starting the study, 5, 15, 30 and 60 minutes after starting the study

Method of measurement

Numeric rating scale (NRS)

Secondary outcomes

1

Description

Patient satisfaction with pain control

Timepoint

2 hours after the start of the study

Method of measurement

Asking verbal

2

Description

Side effects of the treatments

Timepoint

Before starting the study, 5, 15, 30, 60 minutes after starting the study and if the patient has been in the hospital for more than 2 hours; At the time of discharge of the patient.

Method of measurement

Medical history and physical examination

3

Description

Duration of the patient's presence in the emergency department

Timepoint

At the time of discharge of the patient

Method of measurement

Clock

Intervention groups

1

Description

Intervention group: The nurse nebulizes 0.5 mg/kg Ketamine and injects 1 cc / kg normal saline For the patient who is a member of the intervention group.

Category

Treatment - Drugs

2

Description

Control group: The nurse injects 1mg/kg of Ketorolac and 0.5 cc / kg of distilled water is nebulizes for the patient in the control group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hosein hospital in shahrood

Full name of responsible person

Hsoein Amiri largani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahrood University of Medical Sciences

Full name of responsible person

Vice chancellor for research and technology

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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

Shahrood 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

Shahrood University of Medical Sciences

Full name of responsible person

Yasaman Safari

Position

Medical intern

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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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

Undecided - It is not yet known if there will be a plan to make this available

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