Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jun 2026

Comparison of analgesic effects of ketamine-midazolam and apotel-ketorolac in renal colic patients

Protocol summary

Study aim
Comparison of analgesic effects of ketamine-midazolam and apotel-ketorolac in renal colic patients

Design
Randomized clinical trial with 200 samples which randomly divided into groups A and B using ten-person blocks.

Settings and conduct
This study will be conducted in Kowsar Hospital in Sanandaj city. The aim of this study is to compare the analgesic effects of ketamine-midazolam and apotel-ketorolac in renal colic patients. The researcher and the patients are unaware of grouping, therefore the study is double blind.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: renal colic patients whose initial pain is greater than or equal to 8 according to the Numeric Ranking Scale system. Exclusion Criteria: patients with schizophrenia, asthma, cardiovascular disease and hypertension; significant head trauma; pregnancy or suspected; active lung infection; hemodynamic instability; respiratory distress or active hypoxemia; sensitivity to acetaminophen; severe liver failure; active liver disease; active gastric ulcer or its history; any suspicion of active bleeding; sensitivity to NSAIDs or aspirin; patients with kidney disease; taking painkillers (NSAIDs, acetaminophen, opioids) in the last 4 hours; glaucoma; patient's refusal to continue participating in the study; normal urine analysis (UA); inability to understand the concept of NRS system.

Intervention groups
Intervention group: for patients in the intervention group, 0.016 mg / kg midazolam and 0.4 mg / kg ketamine based on body weight are injected. Control group: for patients in the control group, 30 mg Ketorolac and 15 mg apotel based on body weight are injected.

Main outcome variables
The primary outcome is the pain which determined based on NRS, one, five, ten, fifteen, thirty and forty-five minutes after drug injection.

General information

Reason for update
Add a definite start and end date for sampling

Acronym

IRCT registration information
IRCT registration number: **IRCT20200422047163N1**
Registration date: **2020-05-01, 1399/02/12**
Registration timing: **prospective**

Last update: **2021-05-21, 1400/02/31**
Update count: **1**

Registration date
2020-05-01, 1399/02/12

Registrant information

Name
Anvar Bahrami

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 87 3366 4674

Email address
bahramianvar92@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-12-22, 1398/10/01

Expected recruitment end date
2020-08-22, 1399/06/01

Actual recruitment start date
2020-05-04, 1399/02/15

Actual recruitment end date
2020-11-20, 1399/08/30

Trial completion date
2020-11-20, 1399/08/30

Scientific title
Comparison of analgesic effects of ketamine-midazolam and apotel-ketorolac in renal colic patients

Public title
Analgesic effects of ketamine-midazolam and apotel-ketorolac in renal colic patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Renal colic patients whose initial pain is greater than or equal to 8 according to the Numeric Ranking Scale system

Exclusion criteria:
Patients with schizophrenia, asthma, cardiovascular disease and hypertension Significant head trauma Pregnancy or suspected Active lung infection Hemodynamic instability Respiratory distress or active hypoxemia Sensitivity to acetaminophen Severe liver failure Active liver disease Active gastric ulcer or its history Any suspicion of active bleeding Sensitivity to NSAIDs or aspirin Patients with kidney disease Taking painkillers (NSAIDs, acetaminophen, opioids) in the last 4 hours Glaucoma The patient's refusal to continue participating in the study Normal urine analysis (UA) Inability to understand the concept of NRS system

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **200**
Actual sample size reached: **200**

Randomization (investigator's opinion)
Randomized

Randomization description
Samples are randomly divided into groups A and B using ten-person blocks. Based on time for patients referring to emergency room, the first ten patients will be allocated to group A and the next ten will be allocated to group B.This continues until the end of sampling.

Blinding (investigator's opinion)
Double blinded

Blinding description
This is a double blind clinical trial. Patients are unaware of the grouping. Also, the person who is following the patient in terms of response to treatment and pain change (researcher student), does not know the injected drug belongs to intervention or control group.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kurdistan University of Medical Sciences

Street address
Pasdaran St., Kurdistan University of Medical Sciences, Sanandaj, Iran

City
Sanandaj

Province
Kurdistan

Postal code
66177-13446

Approval date
2019-09-08, 1398/06/17

Ethics committee reference number
IR.MUK.REC.1398.120

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

Timepoint
One, five, ten, fifteen, thirty and forty-five minutes after drug injection

Method of measurement
It will be determined based on the Numeric Rating Scale system

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For patients in the intervention group, 0.016 mg / kg midazolam and 0.4 mg / kg ketamine based on body weight are injected.

Category

Treatment - Drugs

2

Description

Control group: For patients in the control group, 30 mg Ketorolac and 15 mg apotel based on body weight are injected.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Kowsar Hospital

Full name of responsible person
Anvar Bahrami

Street address
Kowsaer Hospital, Boranaldin Hamdi Ave.,Sanandaj, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Sanandaj University of Medical Sciences

Full name of responsible person
Afshin Maleki

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Maleki43@yahoo.com

Grant name

Grant code / Reference number

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

Title of funding source
Sanandaj 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
Sanandaj University of Medical Sciences

Full name of responsible person
Anvar Bahrami

Position
Student of Medicine (Intern)

Latest degree
A Level or less

Other areas of specialty/work
General Practitioner

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
Leila Azizkhani

Position
Assistant Professor of Emergency Medicine

Latest degree
Specialist

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Emergency Medicine

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Person responsible for updating data

Contact

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Position
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Latest degree
A Level or less

Other areas of specialty/work
General Practitioner

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Data on the main outcome of the study can be shared.

When the data will become available and for how long
One year after the publication the data will be available.

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
Meta-analysis is allowed on the data of this study.

From where data/document is obtainable
Dr. Anvar Bahrami, Pasdaran St., Kurdistan University of Medical Sciences, Sanandaj, Iran , Email: bahramianvar92@gmail.com

What processes are involved for a request to access data/document
After one year of publishing the article and publishing the results, those who need the data of this study, could apply via email.

Comments