

# 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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Sanandaj

**Province**

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**Postal code**

66179-83476

**Phone**

+98 87 3361 1231

**Email**

bahramianvar92@gmail.com

**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****Name of organization / entity**

Sanandaj University of Medical Sciences

**Full name of responsible person**

Leila Azizkhani

**Position**

Assistant Professor of Emergency Medicine

**Latest degree**

Specialist

**Other areas of specialty/work**

Emergency Medicine

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## Person responsible for updating data

### 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  
**Street address**  
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**Province**  
Kurdistan  
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**Email**  
bahramianvar92@gmail.com

## 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