

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Investigating the effect of piroxicam injection in renal colic

#### Protocol summary

##### Study aim

Determining the effect of piroxicam injection in renal colic patients referred to the emergency department of Imam Khomeini Hospital in Ahvaz in 1402

##### Design

A clinical trial with a control group. with double-blind group, Randomized, on 176 patients

##### Settings and conduct

This study is a double-blind and randomized clinical trial. It will be conducted on the population of all patients with renal colic referred to the emergency department of Imam Khomeini Hospital in Ahvaz in 1402. In this study, using the census sampling method, patients with renal colic who referred in the months of February and March 1402 are selected and examined. Sufficient explanations are provided to them regarding the study method and informed consent is obtained.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: The criteria for entering the study are willingness and cooperation to participate in the study, suffering from renal colic that has been more than 6 months since the diagnosis of the disease by a specialist doctor. Exit criteria: Exclusion criteria are also unwillingness to participate in the study, pregnant women or

##### Intervention groups

Patients are divided into two groups. In the first group (case), piroxicam ampoule will be prescribed, and in the second group (control), the usual treatment will be done for the patients.

##### Main outcome variables

pain

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230808059084N1**

Registration date: **2023-08-20, 1402/05/29**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-08-20, 1402/05/29**

Update count: **0**

##### Registration date

2023-08-20, 1402/05/29

##### Registrant information

###### Name

Mahsa Bagdeli

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 930 729 5540

###### Email address

mahsa.bagdeli99@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-07-23, 1402/05/01

##### Expected recruitment end date

2023-09-06, 1402/06/15

##### Actual recruitment start date

2023-08-06, 1402/05/15

##### Actual recruitment end date

2023-10-23, 1402/08/01

##### Trial completion date

2023-12-22, 1402/10/01

##### Scientific title

Investigating the effect of piroxicam injection in renal colic

##### Public title

Investigating the effect of piroxicam injection in renal colic

##### Purpose

Health service research

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

Desire and cooperation to participate in the study  
Suffering from renal colic for more than 6 months from the diagnosis of the disease by the doctor

**Exclusion criteria:**

Reluctance to participate in the study Pregnant or lactating women

**Age**

No age limit

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator

**Sample size**

Target sample size: **176**

Actual sample size reached: **176**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study, 176 eligible patients will be randomly selected. Then random numbers are created by "Random Allocation" computer software. We randomly divide these numbers into two groups A (first intervention) and B (control). Each number is written on a piece of paper and placed in an envelope. Then each patient is asked to choose one envelope from among the envelopes. Then, according to the selected envelope, the patient is assigned to one of the two groups

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

A clinical care prescribes drugs to patients according to which group they are in. The researchers have no knowledge of the type of drug used and collect the results based on the patient's code. Patients are also unaware of the type of medicine they receive.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Ahvaz University of Medical Sciences

**Street address**

No. 84, Bahnar St

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

11111111111111111111

**Approval date**

2023-07-17, 1402/04/26

**Ethics committee reference number**

IR.AJUMS.REC.1402.238

**Health conditions studied****1****Description of health condition studied**

Patients with renal colic

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Pain score on Visual Analogue Scale

**Timepoint**

Immediately, 15 and 30 minutes after injection

**Method of measurement**

Visual Analogue Scale

**Secondary outcomes****1****Description**

Vital Signs

**Timepoint**

Immediately, 15 and 30 minutes after injection

**Method of measurement**

Visual Analogue Scale

**Intervention groups****1****Description**

Patients receiving piroxicam ampoule 40 mg/ml, one dose, once and intramuscularly from Caspian Tamim Company

**Category**

Treatment - Drugs

**2****Description**

Control group:Patients receiving ketorolac 30 mg/ml in a single dose, once intramuscularly from exir company

**Category**

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**  
Imam khomeini hospital of ahvaz  
**Full name of responsible person**  
Mehsa bagdeli  
**Street address**  
No. 84 Bahonar St  
**City**  
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**Email**  
mahsa.bagdeli99@gmail.com

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**  
Ahvaz University of Medical Sciences  
**Full name of responsible person**  
Maitham Moazi  
**Street address**  
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mahsa.bagdli99@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**  
Mehsa Bagdeli  
**Position**  
doctor  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Medical Education  
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## Person responsible for scientific inquiries

### Contact

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**Other areas of specialty/work**  
General Practitioner  
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## Person responsible for updating data

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mahsa bagdeli  
**Position**  
doctor

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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**Email**

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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