

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 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
Khouzestan
Postal code
111111111111111111

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

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No. 84 Bahonar St

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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

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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

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

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

General Practitioner

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Person responsible for updating data

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

mahsa bagdeli

Position

doctor

Latest degree

Medical doctor

Other areas of specialty/work

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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