

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Comparison of the analgesic efficacy of pethedine and ketorolac in renal colic patients referred to imam khomeini hospital ilam city in 2022

Protocol summary

Study aim

Achieving a longer lasting analgesic effect in renal colic patients

Design

A clinical trial without a control group, with parallel groups, double-blind, randomized, phase 2 on 108 patients, simple randomization method by number table was used for randomization.

Settings and conduct

The location of the study is Imam Khomeini (RA) Ilam Hospital, which is in the field of treating patients with renal colic. First, the pain level of each patient is recorded; Then the patients are randomly divided into 3 groups, the first group is given 25 mg of pethidine, the second group is given 30 mg ketorolac, and the third group is given a combination of 2 drugs. The medicinal solution is given to the patients by a nurse who has no knowledge of the study protocol. There is no information about the medicinal solution of different groups and there is no difference between them. If the verbal score of "no pain" or "much better pain" is not obtained, the life-saving drug pethidine 25mg this time is in the form of iv slow injection to be repeated every 15 minutes if needed. The functional status of the patient is calculated as follows: weak impairment: able to return to work and drive a car; moderate impairment: able to perform daily activities at home; severe impairment: confined to bed.

Participants/Inclusion and exclusion criteria

Eligibility: Renal colic patients with clinical and radiological diagnosis of kidney stones
Exclusion conditions: 1_Pregnant women 2_Nursing mothers 3_Persons with kidney dysfunction before 4_Patients treated with warfarin 5_Patients with bleeding disorders 6_Persons with a history of gastrointestinal problems after taking NSAIDS

Intervention groups

The first group is injected with 25 mg of pethidine the second group is injected with 30 mg of ketorolac and the third group is injected with a combination of ketorolac

and pethidine.

Main outcome variables

Pain relief

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221229056978N1**

Registration date: **2023-02-10, 1401/11/21**

Registration timing: **prospective**

Last update: **2023-02-10, 1401/11/21**

Update count: **0**

Registration date

2023-02-10, 1401/11/21

Registrant information

Name

Amir reza Eidypour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 84 3323 4131

Email address

amir.eidypour@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2023-03-21, 1402/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the analgesic efficacy of pethedine and ketorolac in renal colic patients referred to imam khomeini hospital ilam city in 2022

Public title
Comparison of the analgesic efficacy of pethedine and ketorolac in renal colic patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
All renal colic patients who have been confirmed by clinical and laboratory diagnosis
Exclusion criteria:
Women who are pregnant Breastfeeding mothers
Patients who received sedation less than 6 hours before arrival
People with kidney dysfunction
Patients treated with warfarin
Patients with gastrointestinal disorders after taking NSAIDs

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **108**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are individually divided into 3 groups by a simple randomization method by a table of numbers in such a way that each person is assigned a number according to the table and then randomly any number from the box The number 1 to 108 is placed in it, the first number is placed in the first group, the second number is placed in the second group, and the third number is placed in the third group, and the randomization continues in this way until the end, and none of the patients from The groupings and the difference between the intervention of the groups are no longer known.

Blinding (investigator's opinion)
Double blinded

Blinding description
All patients (participants) are not aware of the groupings and that the injection solution of each group is different, and the solution will be injected by a nurse who will not have any knowledge of the composition of the solution and the difference of the injection solution of different groups.

Placebo
Not used

Assignment

Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Ilam University of Medical Sciences
Street address
Ilam University of Medical Sciences campus.,Pazhouhesh Blvd.,Banganjab.,Ilam
City
Ilam
Province
Ilam
Postal code
6939177134

Approval date
2022-09-19, 1401/06/28

Ethics committee reference number
IR.MEDILAM.REC.1401.133

Health conditions studied

1

Description of health condition studied
Investigation of pain in renal colic patients

ICD-10 code
23

ICD-10 code description
Diseases of the genitourinary system

Primary outcomes

1

Description
Pain level of renal colic patients

Timepoint
Pain measurement before the start of the intervention in all three groups, upon arrival and 35 minutes in the pethidine group, upon arrival and 3 minutes in the ketorolac group, and upon arrival and 35 minutes in the combination solution group of ketorolac and pethidine.

Method of measurement
The method of measurement of the qualitative study is based on the functional status as follows: Weak impairment: able to return to work and drive a car
2_Mild impairment: able to perform daily activities at home
3_Severely injured: confined to bed

Secondary outcomes
empty

Intervention groups

1

Description

Intervention group: The first group receives 25 mg pethidine

Category

Treatment - Drugs

2

Description

Intervention group: The second group receives 30 mg ketorolac

Category

Treatment - Drugs

3

Description

Intervention group: The third group receives a combination solution of pethidine and ketorolac

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital

Full name of responsible person

Amirreza Eidypour

Street address

Ilam, Ayatollah Heydari St

City

Ilam

Province

Ilam

Postal code

6931975397

Phone

+98 87 3333 4500

Email

amir.eidypour@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ilam University of Medical Sciences

Full name of responsible person

Abas Maleki

Street address

Ilam University of Medical Sciences
campus.,Pazhouhesh Blvd.,Banganjab.,Ilam

City

Ilam

Province

Ilam

Postal code

6939177143

Phone

+98 84 3222 7103

Email

amir.eidypour@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ilam 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

Ilam University of Medical Sciences

Full name of responsible person

Hosein Seyedkhani

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Biostatistics

Street address

Ilam University of Medical Sciences
campus.,Pazhuhesh Blvd.,Banganjab.,Ilam Town

City

Ilam

Province

Ilam

Postal code

6939177143

Phone

+98 84 3222 7134

Email

hseidkhani@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ilam University of Medical Sciences

Full name of responsible person

Aref Teymourinejad

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Urology

Street address

No.7,Taqavi dead end.,Nehzat Ave.,Ilam Town

City

Ilam

Province

Ilam

Postal code

61931854443

Phone

+98 84 3222 7154

Email

arefteymourinejad@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Ilam University of Medical Sciences

Full name of responsible person

Amirreza Eidypour

Position

medical student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

Street behind veterinary medicine

City

Eyvan

Province

Ilam

Postal code

6941644883

Phone

+98 84 3323 4131

Email

amir.eidypour@gmail.com

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