Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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