

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Comparing the analgesic effect of paracetamol and ketorolac VS morphine in renal colic; A randomized controlled trial

Protocol summary

Study aim

Comparing the analgesic effect of paracetamol and ketorolac with morphine in patients with kidney colic.

Design

Clinical trial consisting of the control group, with parallel groups, double blind-third phase with 30 patients. The block randomization is being used.

Settings and conduct

Emergency of Imam Reza hospital

Participants/Inclusion and exclusion criteria

Including criteria: Age higher than 18 and lower than 65. Pain in the flank both clinically or paraclinical. NRS more than 3 Don't get pain killer for 6 hours. GCS=15 Entering only once. Excluding criteria: Unknown kidney, liver, or heart failure Sensitivity to opioids, paracetamol, or ketorolac Pregnancy Patients with transformed organ Unstable vital signs; systolic blood pressure of lower than 90 mmHg Signs of stimulation of peritoneum

Intervention groups

The first group (control group): Morphine was infused with the dose of 0.1 mg/kg intravenously (IV) with N/S 100 cc in 15 min. The second group: Ketorolac was infused with the dose of 30 mg IV and paracetamol with the dose of 1000 mg with N/S 100 cc in 15 min.

Main outcome variables

Analgesic effect

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220108053669N1**

Registration date: **2022-01-16, 1400/10/26**

Registration timing: **prospective**

Last update: **2022-01-16, 1400/10/26**

Update count: **0**

Registration date

2022-01-16, 1400/10/26

Registrant information

Name

Peyman Esmaeili Fard Barzegar

Name of organization / entity

Lorestan University

Country

Iran (Islamic Republic of)

Phone

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Email address

esmaeili.pe@fv.lu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-21, 1400/11/01

Expected recruitment end date

2022-03-21, 1401/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the analgesic effect of paracetamol and ketorolac VS morphine in renal colic; A randomized controlled trial

Public title

Comparing the effect of the combination of two pain killers with morphine in patients with flank pain

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Pain in flank clinically or paraclinically NRS less than 3 Don't taking pain killer in 6 hours GCS=15 Entering only for once Exclusion criteria: Unknown kidney, liver or heart failure Sensitivity to opioids, paracetamol or ketorolac Pregnancy patients with transformed organs Unstable vital signs; systolic blood pressure of lower than 90 mmHg Sings of inflamed peritoneum Age From 18 years old to 65 years old Gender Both Phase 3 Groups that have been masked • Participant • Care provider • Outcome assessor Sample size Target sample size: 30 Randomization (investigator's opinion) Randomized Randomization description The patients are grouped into two groups through block randomization. There are 4 blocks in which two special are for the sham group and two special blocks are for the control group and the numbers are determined randomly by computer. Blinding (investigator's opinion) Double blinded Blinding description The drugs are prepared by the emergency staff who doesn't have any other impact on this study. The drugs are packed in similar packages in which they can only distinguish by numbers and they are administered by a nurse who doesn't know of the ingredients. According to the patients' order and through the random block is administered by emergency nurses who are not aware of the component. After administration, the intern will submit the amount of pain, in which they don't know the groups either, in 0, 15, and 30 minutes after administration by a numerical rating scale. If after 30 min the patients would have intolerable pain, by the doctor's permission, they will get a fentanyl dose. Placebo Not used Assignment Parallel Other design features Secondary Ids empty Ethics committees 1 Ethics committee	Name of ethics committee Ethics committee of Kermanshah University of Medical Sciences Street address Shahid Beheshti blvd City Kermanshah Province Kermanshah Postal code 6715847141 Approval date 2021-12-19, 1400/09/28 Ethics committee reference number IR.KUMS.REC.1400.634
	Health conditions studied 1 Description of health condition studied Pain in the flank - Kidney problem ICD-10 code ICD-10 code description Primary outcomes 1 Description The amount of pain Timepoint 15 minutes Method of measurement Questionnaire Secondary outcomes 1 Description Vomiting Timepoint Every 15 minutes Method of measurement Questionnaire 2 Description Vertigo Timepoint Every 15 minutes Method of measurement Questionnaire 3 Description Hypotension Timepoint Every 15 minutes

Method of measurement

Measuring

Intervention groups

1

Description

Intervention group: Ketorolac and paracetamol with a dose of 30 mg IV and 1000 mg IV, respectively, is infused with 100 cc N/S in 15 min.

Category

Prevention

2

Description

Control group: Morphine with a dose of 0.1 mg/kg IV is infused with 100 cc N/S in 15 min.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza hospital

Full name of responsible person

Mohammad Reza Farnia

Street address

Shahid Beheshti blvd

City

Kermanshah

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6715847141

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

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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

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Mohammad Reza Farnia

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available