Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
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Name of organization / entity
Lorestan University
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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
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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
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Specialist
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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