Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

Effect of paracetamol and ketorolac versus paracetamol and ibuprofen on the pain in patients with renal colic: a triple-blind randomized clinical trial

Protocol summary

Study aim

To assess the effect of paracetamol and ketorolac versus paracetamol and ibuprofen on the pain in patients with renal colic

Design

This is a triple-blind randomized clinical trial, phase II, in which 80 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible patients with renal colic referring to the Besat Hospital in Hamadan city during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the block randomization. This trial will be double-blinded so that neither patients nor the physician examining the patients and data analyzer will be aware of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 60 years, Renal colic, Pain score of 5 or higher, Conscious level equal to 15
Exclusion criteria: Pregnancy, Cardiovascular failure, Chronic liver failure, Renal failure, Anemia, Peritonitis, Hemodynamics unsuitability, Sensitivity to morphine or its extension, History of allergy to ketorolac or ibuprofen, Receiving analgesic medications in the past 6 hours

Intervention groups

Intervention group 1: Intravenous injection of ketorolac 30 mg (manufactured by Alborz Pharmaceutical Co.) with 10 ml distilled water plus intravenous infusion of paracetamol 1 g (manufactured by Abidi Pharmaceutical Co.) with 100 ml serum normal saline. Intervention group 2: Intravenous injection of ibuprofen 400 mg (manufactured by Abidi Pharmaceutical Co.) with 10 ml distilled water plus intravenous infusion of paracetamol 1 g (manufactured by Abidi Pharmaceutical Co.) with 100 ml serum normal saline.

Main outcome variables

Primary outcome: The severity of renal colic

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N341**
Registration date: **2020-03-03, 1398/12/13**
Registration timing: **retrospective**

Last update: **2020-03-03, 1398/12/13**
Update count: **0**

Registration date

2020-03-03, 1398/12/13

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 81 1838 0090

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-30, 1398/11/10

Expected recruitment end date

2020-02-29, 1398/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effect of paracetamol and ketorolac versus paracetamol and ibuprofen on the pain in patients with renal colic: a triple-blind randomized clinical trial

Public title
Effect of paracetamol and ketorolac versus paracetamol and ibuprofen on the pain in patients with renal colic

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age of 18 to 60 years, Renal colic, Pain score of 5 or higher, Conscious level equal to 15

Exclusion criteria:
Pregnancy, Cardiovascular failure, Chronic liver failure, Renal failure, Anemia, Peritonitis, Hemodynamics unsuitability, Sensitivity to morphine or its extension, History of allergy to ketorolac or ibuprofen, Receiving analgesic medications in the past 6 hours

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

Blinding (investigator's opinion)
Triple blinded

Blinding description
The drugs will be given in coded envelopes. The shape of the medications and placebos will be perfectly the same. Therefore, patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. The analyzer will be unaware of the type of interventions Thus, the trial will be run as triple-blind.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Hamadan University of Medical Sciences

Street address
Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City
Hamadan

Province
Hamadan

Postal code
6517838695

Approval date
2020-01-25, 1398/11/05

Ethics committee reference number
IR.UMSHA.REC.1398.949

Health conditions studied

1

Description of health condition studied
Renal colic

ICD-10 code
N23

ICD-10 code description
Unspecified renal colic

Primary outcomes

1

Description
The severity of renal colic

Timepoint
At the zero, 30, and 60 minutes after the intervention

Method of measurement
By using Visual Analog Scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Intravenous injection of ketorolac 30 mg (manufactured by Alborz Pharmaceutical Co.) with 10 ml distilled water plus intravenous infusion of paracetamol 1 g (manufactured by Abidi Pharmaceutical Co.) with 100 ml serum normal saline.
Category
Treatment - Drugs

2

Description
Intervention group 2: Intravenous injection of ibuprofen 400 mg (manufactured by Abidi Pharmaceutical Co.) with 10 ml distilled water plus intravenous infusion of paracetamol 1 g (manufactured by Abidi Pharmaceutical Co.) with 100 ml serum normal saline.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Besat Hospital in Hamadan city
Full name of responsible person
Dr Sanaz Farsadnia
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person
Dr Sanaz Farsadnia
Position
Resident of Emergency Medicine
Latest degree
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Person responsible for updating data

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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