

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)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

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

Besat Hospital, Shahed Square

City

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Province

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6517838695

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+98 81 3364 0030

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drsanz1398@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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6517838695

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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

Medical doctor

Other areas of specialty/work

Emergency Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Reasoul Salimi

Position

Specialist in Emergency Medicine

Latest degree

Medical doctor

Other areas of specialty/work

Emergency Medicine

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

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

Street address

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City**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