Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

A comparative study of the effect of intravenous ibuprofen and intravenous ketorolac in controlling the pain of renal colic patients .

Protocol summary

Study aim
Determining and comparing the effect of intravenous ibuprofen with intravenous ketorolac in controlling the pain of renal colic patients

Design
Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 76 patients. The rand function of Excel software is used for randomization

Settings and conduct
In this study, we investigate the effect of two NSAIDs, i.e. intravenous ibuprofen and intravenous ketorolac, in renal colic patients referred to the emergency room of Shahid Beheshti Hospital. This study is double-blind, and blinding will be done on the patient and health personnel. It is a clinical trial.

Participants/Inclusion and exclusion criteria
All patients with flank pain (renal colic) and definitive diagnosis of renal colic with imaging findings by non-contrast CT scan or ureteral ultrasound, who are between 18 and 60 years old, are included in this study.Patients with a history of renal failure (CRF), pregnant women, history of liver disease, history of gastrointestinal disease such as active GI bleeding, history of heart disease (HF), history of sensitivity to NSAID are excluded from the study.

Intervention groups
After explaining the objectives of the study to the patients and obtaining informed consent, the patients are divided into two groups using the balanced block random sampling method, each treatment group has 38 people; The first group of 38 people received intravenous ketorolac In both groups, the injection will be done as a single-dose intravenous infusion for 30 minutes with cardiac and respiratory monitoring.

Main outcome variables
drug side effects; The amount of opioid medication needed

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231112060025N1**
Registration date: **2023-12-04, 1402/09/13**
Registration timing: **prospective**

Last update: **2023-12-04, 1402/09/13**
Update count: **0**

Registration date
2023-12-04, 1402/09/13

Registrant information

Name
Atefe Noormohammadi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 25 3661 0690

Email address
atefenrm5@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-12-22, 1402/10/01

Expected recruitment end date
2024-06-21, 1403/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

A comparative study of the effect of intravenous ibuprofen and intravenous ketorolac in controlling the pain of renal colic patients .

Public title
"comparative effect of Ibuprofen and ketorolac in Renal colic"

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with flank pain (renal colic) who have Definitive diagnosis of renal colic with imaging findings by non-contrast CT scan or ureteral ultrasound. Age between 18 and 60 years

Exclusion criteria:
History of renal failure Pregnant women History of liver disease History of gastrointestinal disease such as active GI bleeding History of heart disease History of sensitivity to NSAID

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **76**

Randomization (investigator's opinion)
Randomized

Randomization description
After explaining the objectives of the study to the patients and obtaining informed consent, the patients are divided into two groups using the balanced block random sampling method.Patients are divided into two groups using the randomized balanced block method with block sizes of 4 and 6. The random sequence is generated by an epidemiologist by running an online program on the website (https://www.sealedenvelope.com). Allocation concealment is also guaranteed due to the use of special codes generated by the website

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study ; For the patient and the health personnel (who are responsible for the patient's care), an explanation will be given about both drugs included in the study, and the possible benefits and side effects of each injection will be explained. However, the patient and the health personnel about which of the two drugs will be prescribed; In the two study groups, they will be unaware of which drug; will be injected for the patient; are informed

Placebo
Not used

Assignment
Parallel

Other design features
In both groups, the injection will be done as a single-dose intravenous infusion for 30 minutes with cardiac and respiratory monitoring.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Qom University of Medical Sciences

Street address
No. 83, Shahid Lotfi Niaser Ave, Safashehr Blvd

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Province
Ghoum

Postal code
3719964797

Approval date
2023-01-30, 1401/11/10

Ethics committee reference number
IR.MUQ.REC.1401.231

Health conditions studied

1

Description of health condition studied
Renal colice

ICD-10 code
N23

ICD-10 code description
Unspecified renal colic

Primary outcomes

1

Description
Severity of pain caused by renal colic using a numerical scale

Timepoint
at minute zero; 20 minutes after injection; 60 minutes after injection

Method of measurement
VAS scale

Secondary outcomes

1

Description
Time to release and relieve pain

Timepoint

at minute zero; 20 minutes after injection; 60 minutes after injection

Method of measurement

Pre-designed questionnaire

Intervention groups

1

Description

intervention group: including 38 patients; 30 mg intravenous Ketorlak will be administered as a single-dose intravenous infusion for 30 minutes with cardiac and respiratory monitoring.

Category

Treatment - Drugs

2

Description

Intervention group: 38 people intravenous ibuprofen 400 mg will be injected in both groups as a single dose intravenous infusion for 30 minutes along with cardiac and respiratory monitoring.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti hospital

Full name of responsible person

Atefe Noormohammadi

Street address

Beheshti Hospital, Beheshti Blvd, Qom, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ghoum 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

Ghoum 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

Ghoum University of Medical Sciences

Full name of responsible person

Atefe NoorMohammadi

Position

Medical student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Mohammad Shahidi

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Emergency Medicine

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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