

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 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 .		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.	
Public title	"comparative effect of Ibuprofen and ketorolac in Renal colic"	Secondary Ids	empty
Purpose	Treatment	Ethics committees	
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	1	
Gender	Both	Ethics committee	
Phase	3	Name of ethics committee	Research Ethics Committees of Qom University of Medical Sciences
Groups that have been masked	- Participant - Care provider	Street address	No. 83, Shahid Lotfi Niaser Ave, Safashehr Blvd
Sample size	Target sample size: 76	City	Qom
Randomization (investigator's opinion)	Randomized	Province	Ghoum
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	Postal code	3719964797
Blinding (investigator's opinion)	Double blinded	Approval date	2023-01-30, 1401/11/10
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	Ethics committee reference number	IR.MUQ.REC.1401.231
Placebo	Not used	Health conditions studied	
Assignment	Parallel	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 Ketorolac 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

City

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Province

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Postal code

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ghoum University of Medical Sciences

Full name of responsible person

Rahim Aali

Street address

No. 83, Shahid Lotfi Niaser Ave, Safashehr Blvd

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Province

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3716993456

Phone

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rahimalii@yahoo.com

Web page address

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

Ghoum University of Medical Sciences

Full name of responsible person

Mohammad Shahidi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

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Atefe NoorMohammadi

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Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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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