Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Evaluation of the effect of ibuprofen injection compared to ketorolac injection in improving renal colic pain of out patients after entering the emergency department

Protocol summary

Study aim
Evaluation of the effect of ibuprofen injection compared to ketorolac injection in improving renal colic pain

Design
A parallel-group, double-blind, randomized, phase 3 clinical trial on 100 patients. Random number generation program will be used for randomization.

Settings and conduct
This clinical trial study will be conducted in Golestan Hospital in Ahvaz on patients diagnosed with renal colic.Patients are divided into two groups receiving intravenous ibuprofen or ketorolac, and the pain level is measured at 0, 20, 40, and 60 minutes later.

Participants/Inclusion and exclusion criteria
This study will be conducted on acute renal colic pain caused by kidney stones.The entry criteria include urinalysis test (U/A), ultrasound observation based on the presence of mild and moderate hydronephrosis and a history of similar symptoms, rejection of other differential ultrasound diagnoses, and informed consent and the non-entry criteria includes patients who are candidates for surgical intervention and patients with large stone size.

Intervention groups
The first group received a dose of 800 mg of intravenous ibuprofen in 250 cc of normal saline within 5 minutes to determine the pain intensity at 0, 20, 40, and 60 minutes after the injection. The second group received a dose of 30 mg of intravenous ketorolac in 250 cc of normal saline within 5 minutes to determine the pain intensity at 0, 20, 40 and 60 minutes after the injection.

Main outcome variables
pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230726058930N1**
Registration date: **2023-10-18, 1402/07/26**
Registration timing: **registered_while_recruiting**

Last update: **2023-10-18, 1402/07/26**
Update count: **0**

Registration date
2023-10-18, 1402/07/26

Registrant information

Name
Ali Vefagh Nematollahi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 61 3367 5436

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vefagh.a@ajums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-09-23, 1402/07/01

Expected recruitment end date
2025-03-19, 1403/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of ibuprofen injection compared

to ketorolac injection in improving renal colic pain of out patients after entering the emergency department

Public title
Ibuprofen compared to ketorolac in improving renal colic pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients referred to the emergency center with acute renal colic pain caused by kidney stones Diagnosis of renal colic by an emergency medicine specialist considering clinical examination, urinalysis test (U/A), ultrasound based on the presence of mild and moderate hydronephrosis and rule out other differential diagnoses
Exclusion criteria:
Patients with coagulation disorders chronic kidney disease (CKD) severe hydronephrosis active gastrointestinal bleeding (GIB) patients who do not respond to treatment up to 30 minutes after drug injection patients who are candidates for surgical intervention patients with large stone size
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are randomly assigned to two intervention groups using randomized block method. For this purpose, blocks of four are prepared and the name of the first intervention is written on two sheets and the name of the second intervention is written on the other two sheets. The sheets are piled up and placed in the container, and one sheet is pulled out for each patient without placing it. Then four sheets are returned to the container and this process is repeated until the sample volume is reached.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Ahvaz University of Medical Sciences
Street address
Emergency Medicine Department Office- Golestan Hospital- Golestan (Farvardin St.)- Ahvaz
City
Ahvaz
Province
Khouzestan
Postal code
15794 - 61357
Approval date
2023-07-17, 1402/04/26
Ethics committee reference number
IR.AJUMS.REC.1402.242

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
pain
Timepoint
0, 20, 40, 60 minutes after injection
Method of measurement
Numeric Pain Rating Scale (NRS)

Secondary outcomes

1

Description
blood pressure
Timepoint
After injection of painkillers
Method of measurement
Blood pressure measuring device

2

Description
Shortness of breath
Timepoint
After injection of painkillers
Method of measurement
Borg shortness of breath scale

3

Description
heart beat
Timepoint
After injection of painkillers
Method of measurement
Using a sphygmomanometer

4

Description
nausea
Timepoint
After injection of painkillers
Method of measurement
Ask the patient

Intervention groups

1

Description
Intervention group: The first group received a dose of 800 mg of intravenous ibuprofen in 250 cc of normal saline within 5 minutes to determine the pain intensity at 0, 20, 40, and 60 minutes after the injection.
Category
Treatment - Drugs

2

Description
Intervention group: The second group received a dose of 30 mg of intravenous ketorolac in 250 cc of normal saline within 5 minutes to determine the pain intensity at 0, 20, 40 and 60 minutes after the injection.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeyni Hospital
Full name of responsible person
Ali Vefagh Nematollahi
Street address
Imam Khomeini Medical Education Center Ahvaz- Azadegan St.- Ahvaz
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2

Recruitment center
Name of recruitment center
Golestan Hospital
Full name of responsible person
Ali Vefagh Nematollahi
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Sponsors / Funding sources

1

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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
Ahvaz 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
Ahvaz University of Medical Sciences

Full name of responsible person
Ali Vefagh nematollahi

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Emergency Medicine

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Specialist

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Person responsible for updating data

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Specialist

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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 further 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