Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jul 2026

Comparison of intravenous ibuprofen and intravenous ketorolac in renal colic pain reduction in the emergency department

Protocol summary

Study aim
Comparison of the effect of intravenous ibuprofen plus intravenous morphine and intravenous ketorolac plus intravenous morphine in decreasing pain intensity of renal colic patients

Design
Phase 3 triple blinded randomized clinical trial with a control group. Sample size: 195 patients.

Settings and conduct
This study will be conducted in Sina Hospital in Tehran, Iran, which is an academic hospital. The emergency department sees 35000 patient annually.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with renal colic who present to the emergency department and their pain intensities are equal or greater than 7 out of 10 Exclusion criteria: Patients who are below 18 years old, above 65 years old, weigh below 50 kilograms, or there is a risk of adverse events following NSAIDs or morphine administration will be excluded from the study.

Intervention groups
The first intervention group (group I): 5 mg intravenous morphine sulfate in 5 minutes + 800 mg intravenous ibuprofen in 200 milliliters normal saline in 30 minutes + 2 milliliters intravenous distilled water in 30 seconds The second intervention group (group K): 5 mg intravenous morphine sulfate in 5 minutes + 200 milliliters intravenous normal saline in 30 minutes + 30 mg intravenous ketorolac (equals to 2 milliliters) distilled water in 30 seconds The control group (group M): 5 mg intravenous morphine sulfate in 5 minutes + 200 milliliters intravenous normal saline in 30 minutes + 2 milliliters intravenous distilled water in 30 seconds

Main outcome variables
Pain intensity; adverse events; patients' stay in ED

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150213021063N5**
Registration date: **2019-01-15, 1397/10/25**
Registration timing: **registered_while_recruiting**

Last update: **2019-01-15, 1397/10/25**
Update count: **0**

Registration date
2019-01-15, 1397/10/25

Registrant information

Name
Arash Safaie

Name of organization / entity
Tehran University of Medical Scieces- Sina Hospital

Country
Iran (Islamic Republic of)

Phone
+98 216312413

Email address
a-safaie@sina.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-10-23, 1397/08/01

Expected recruitment end date
2019-03-20, 1397/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of intravenous ibuprofen and intravenous ketorolac in renal colic pain reduction in the emergency

department

Public title
Comparison of intravenous ibuprofen and intravenous ketorolac in renal colic pain reduction
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with renal colic who present to the emergency department and their pain intensities are equal or greater than 7 out of 10
Exclusion criteria:
History of an allergic reaction to ASA or other NSAIDs (including asthma, skin reactions, anaphylaxis, or ...) Known chronic kidney disease Age below 18 or above 65 years Weight below 50 kilograms Peptic ulcer disease history Gastrointestinal bleeding history Suspected volume deficit (based on mucous membranes) Any active bleeding Bleeding diathesis Using anticoagulant or antiplatelet drugs Known heart failure Pregnancy Lactation Systolic blood pressure lower than 100 mmHg
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **195**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be assigned to groups K, I, or M based on the random table which has been developed using hhtp://randome.org website.
Blinding (investigator's opinion)
Triple blinded
Blinding description
Placebo will be used in each of the groups for blinding. Drug administration will be done by someone who has no role in data collection. Patients, data collector and statistical analyst will be blinded to the prescribed drug.
Placebo
Used
Assignment
Factorial
Other design features
If a patient's pain intensity is equal or greater than 7 out of 10 after 30 minutes of drug administration, 5 milligrams intravenous morphine sulfate will be administered to the patients slowly in 5 minutes.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tehran University of Medical Sciences medicine faculty ethics committee
Street address
Building No 1- Northern gate of the university- Poursina street- Qods street- Enghelab avenue.
City
Tehran
Province
Tehran
Postal code
1419733151
Approval date
2017-08-06, 1396/05/15
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1396.3073

Health conditions studied

1

Description of health condition studied
Unspecified renal colic
ICD-10 code
N23
ICD-10 code description
Unspecified renal colic

Primary outcomes

1

Description
Pain intensity
Timepoint
Before drug administration, 30, 60, and 120 minutes after drug administration
Method of measurement
Numeric rating scale

2

Description
Adverse events
Timepoint
Patients will be monitored continuously for adverse events since drug administration till patient discharge.
Method of measurement
Specific occurred adverse event

3

Description
Patient's length of stay
Timepoint
At the time of patient discharge
Method of measurement

Minutes

Secondary outcomes

empty

Intervention groups

1

Description
The first intervention group (group I): 5 mg intravenous morphine sulfate in 5 minutes + 800 mg intravenous ibuprofen in 200 milliliters normal saline in 30 minutes + 2 milliliters intravenous distilled water in 30 seconds
Category
Treatment - Drugs

2

Description
The second intervention group (group K): 5 mg intravenous morphine sulfate in 5 minutes + 200 milliliters intravenous normal saline in 30 minutes + 30 mg intravenous ketorolac (equals to 2 milliliters) distilled water in 30 seconds
Category
Treatment - Drugs

3

Description
Control group (group M): 5 mg intravenous morphine sulfate in 5 minutes + 200 milliliters intravenous normal saline in 30 minutes + 2 milliliters intravenous distilled water in 30 seconds
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina hospital
Full name of responsible person
Dr Arash Safaie
Street address
Hassan Abad square
City
Tehran
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Tehran
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1136746911
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+98 21 6312 1413
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Shahin Akhondzadeh Basti
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Building No 1- Northern gate of the university- Poursina street- Qods street- Enghelab avenue.
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Postal code
1419733151
Phone
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Email
s.akhond@neda.net
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Arash Safaie
Position
Assistant professor of emergency medicine
Latest degree
Specialist
Other areas of specialty/work
Emergency Medicine
Street address
Emergency Department, Sina Hospital, Hassan Abad square.
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a-safaie@sina.tums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Arash Safaie

Position
Assistant professor of emergency medicine

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Person responsible for updating data

Contact

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Tehran University of Medical Sciences

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All unidentified IPD and statistical analyses are sharable.

When the data will become available and for how long
Starting 1 months after publication

To whom data/document is available
Data will be available for academic, scientific, or industrial institutes researchers.

Under which criteria data/document could be used
Data will be shared upon Written request of the individual researcher or the institute.

From where data/document is obtainable
Data will be shared by sending email to Arash Safaie. Email: a-safaie@sina.tums.ac.ir

What processes are involved for a request to access data/document
Data will be shared by sending email to Arash Safaie. We will try our best to send you the requested data as soon as possible.

Comments