

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 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 Sciences- 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 <http://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

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

Province

Tehran

Postal code

1136746911

Phone

+98 21 6312 1413

Email

a-safaie@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Shahin Akhondzadeh Basti

Street address

Building No 1- Northern gate of the university- Poursina street- Qods street- Enghelab avenue.

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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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Phone

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Fax

Email

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

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Contact

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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