

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

The comparison of the efficacy of intravenous ketorolac and ibuprofen in pain reduction in patients with acute low back pain presenting to the emergency department of Sina, Imam Khomeini and Shariati Hospitals in Tehran

Protocol summary

Study aim

The comparison of the efficacy and adverse effects of intravenous ketorolac and ibuprofen in the pain management of patients with acute low back pain

Design

Two arm parallel group randomised trial and triple blinded

Settings and conduct

This is a triple blind study (patient, researcher and data statistician) in a way that the two medications applied in this study are colorless, odorless and prepared with the same volume and infused to the patients. The medications are prepared by a nurse who is not involved in the treatment or gathering the research information and the random code of the infused medication will be documented in the questionnaires. The data analyzer will assess the encoded data. The study will be implemented in the emergency department of Sina, Imam-Khomeini and Shariati hospitals in Tehran.

Participants/Inclusion and exclusion criteria

Participants are patients with acute low back pain (LBP) that did not report their pain for more than 3 months due to musculoskeletal or isolated trauma to the back. Furthermore, patients with increasing low back pain will be included in this study. Inclusion criteria: 1. Patients over 18 years-old 2. Patients with the complaint of musculoskeletal or isolated traumatic LBP 3. Patients having consented to enter the study Exclusion criteria: 1. Patients who have contraindications for Non-steroidal anti-inflammatory drugs (NSAIDs) 2. Pregnancy 3. Multiple trauma patients

Intervention groups

Group 1: Intravenous Ibuprofen: The administration of 2 cc sterile water in 30 seconds and then, 800 mg Ibuprofen in 500 cc normal saline in 30 minutes. Group 2: Intravenous Ketorolac: The administration of 30 mg

Ketorolac in 2 cc syringe in 30 seconds and then, 500 cc normal saline in 30 minutes

Main outcome variables

pain score; drug adverse effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151113025025N2**

Registration date: **2018-09-30, 1397/07/08**

Registration timing: **prospective**

Last update: **2018-09-30, 1397/07/08**

Update count: **0**

Registration date

2018-09-30, 1397/07/08

Registrant information

Name

Maryam Bahreini

Name of organization / entity

Tehran University of Medical Sciences, Sina Hospital

Country

Iran (Islamic Republic of)

Phone

+98 21 6312 1413

Email address

m-bahreini@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-23, 1397/08/01

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of the efficacy of intravenous ketorolac and ibuprofen in pain reduction in patients with acute low back pain presenting to the emergency department of Sina, Imam Khomeini and Shariati Hospitals in Tehran

Public title

The comparison of the efficacy of intravenous ketorolac and ibuprofen in pain reduction in patients with acute low back pain presenting to the emergency department of Sina, Imam Khomeini and Shariati Hospitals in Tehran

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

1. Patients who are over 18 years old. 2. Patients with low back pain due to musculoskeletal or isolated trauma to the back who present to the emergency department. 3. Patients who have completed ethical consent form to enter the study.

Exclusion criteria:

1. Patients who have contraindications for Non-steroidal anti-inflammatory drug (NSAIDs) administration including peptic ulcer, gastrointestinal bleeding, uncontrolled hypertension, renal disease, inflammatory bowel disease, hypersensitivity or allergy to NSAIDs, asthma 2. Pregnancy 3. Patients suffering from multiple trauma.

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Ketorolac and Ibuprofen ampules are prepared and placed in a 4 block sequence that is prepared by a nurse who knows the drug sequences according to a computerized random pattern but does not collect the results. These medications are restored in nearly 27 c in the emergency department. Then, the treating physician orders the next code analgesic from the block that will be infused according to the protocol we arranged. The

treating physician documents the patients' demographic information and the diagnosis in the questionnaire form with the unique code of the medication that the patients received.

Blinding (investigator's opinion)

Triple blinded

Blinding description

This is a triple blind study (patient, researcher and data statistician) in a way that the two medications applied in this study are colorless, odorless and prepared with the same volume and infused to the patients so that they are indistinguishable. The medications are prepared by a nurse who is not involved in the treatment or gathering the research information and the random code of the infused medication will be documented in the questionnaires. The data analyzer will assess the encoded data and will not be informed of the medications. The analgesics of this study are as follows: - Intravenous Ibuprofen: The administration of 2 cc sterile water in 30 seconds and then, 800 mg Ibuprofen in 500 cc normal saline in 30 minutes. - Ketorolac: The administration of 30 mg Ketorolac in 2 cc syringe in 30 seconds and then, 500 cc normal saline in 30 minutes

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences

Street address

Emergency Department, Sina Hospital, Imam-Khomeini Ave., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1136746911

Approval date

2018-09-06, 1397/06/15

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1397.389

Health conditions studied**1****Description of health condition studied**

Acute low back pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain reduction

Timepoint

At the entrance to the emergency department, after 10, 30 and 60 minutes

Method of measurement

Pain intensity measured by Numeric rating scale

2

Description

Medication adverse effects

Timepoint

In the observation time

Method of measurement

Patient complaints of adverse effects during observation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intravenous Ibuprofen

Category

Treatment - Drugs

2

Description

Intervention group: Intravenous Ketorolac

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina hospital

Full name of responsible person

Maryam Bahreini

Street address

Emergency department, Sina hospital, Imam-Khomeini Ave., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1136546911

Phone

+98 21 6312 1413

Email

bahreiniMaryam@gmail.com

2

Recruitment center

Name of recruitment center

Imam-Khomeini hospital

Full name of responsible person

Maryam Bahreini

Street address

Imam-Khomeini hospital, Keshavarz Blvd., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6690 4848

Email

bahreiniMaryam@gmail.com

3

Recruitment center

Name of recruitment center

Shariati hospital

Full name of responsible person

Maryam Bahreini

Street address

Shariati hospital, Jalale-Ale-ahmad Ave., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1411713135

Phone

+98 21 84901

Email

bahreiniMaryam@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Ali Sahraian

Street address

Vice Chancellor of Research and Technology, Qods Ave., Keshavarz Blvd., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 8163 3698

Email

msahrai@tums.ac.ir

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

Maryam Bahreini

Position

Consultant

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

Street address

Emergency department, Sina hospital, Imam-Khomeini Ave., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1136546911

Phone

+98 21 6312 1413

Email

bahreini maryam@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Maryam Bahreini

Position

Consultant

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

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Province

Tehran

Postal code

1136546911

Phone

+98 21 6312 1413

Email

bahreini maryam@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Maryam Bahreini

Position

Consultant

Latest degree

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Email

bahreini maryam@gmail.com

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

Yes - There is 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

Yes - There is 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

Title and more details about the data/document

All data can be exposed anonymously.

When the data will become available and for how long

In the review process of the article

To whom data/document is available

Data will be only accessible for the researchers in the educational institutes.

Under which criteria data/document could be used

If the reviewers of journals request for the data, it will be sent for them anonymously.

From where data/document is obtainable

People can reach the data via an email request by declaring their rationale.

What processes are involved for a request to access data/document

People can reach the data via an email request by declaring their rationale. Data will be accessible in approximately 1 week by the researchers or reviewers.

Comments