# 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**
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**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
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**Province**
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### 2

**Recruitment center**
**Name of recruitment center**
Imam-Khomeini hospital
**Full name of responsible person**
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**Street address**
Imam-Khomeini hospital, Keshavarz Blvd., Tehran, Iran
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### 3

**Recruitment center**
**Name of recruitment center**
Shariati hospital
**Full name of responsible person**
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Shariati hospital, Jalale-Ale-ahmad Ave., Tehran, Iran
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## 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
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**Phone**
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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**
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

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## Person responsible for scientific inquiries

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**Other areas of specialty/work**
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## Person responsible for updating data

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**Latest degree**
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**Other areas of specialty/work**
Emergency Medicine

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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**
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**