

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### Comparison of intravenous ketorolac versus intravenous morphine on pain relief in spinal traumatic patients: a double blind randomized controlled trial

#### Protocol summary

##### Summary

Objectives: To assess the effect of intravenous ketorolac versus intravenous morphine on pain relief in spinal traumatic patients. Design: A double blind randomized clinical trial. Setting and conduct: The eligible spinal traumatic patients who will refer to Besat Hospital during the study period will be enrolled into the trial. Inclusion criteria: Age of 15 to 66 years; spinal trauma. Exclusion criteria: Pregnancy or breastfeeding; narcotic and alcohol addiction; thoracic pain; hemorrhage; low consciousness; liver disease; communication disorders. Intervention group: Infusion of ketorolac 30 mg in 100 normal saline for 15 minutes. Control group: Infusion of morphine 1 mg/kg in in 100 normal saline for 15 minutes. Primary outcome: Assessing pain before intervention and 5, 15, 30, 45 and 60 minutes after intervention using visual analog scale. Randomization: Random assignment of the patients to the intervention and control groups through drawing of lots. Blinding: Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Therefore, the trial will be run as double blind.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201705139014N162**  
Registration date: **2017-05-31, 1396/03/10**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-05-31, 1396/03/10

##### Registrant information

##### Name

Jalal Poorolajal

##### Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan  
University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 1838 0090

##### Email address

poorolajal@umsha.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice-chancellor for Research and Technology, Hamadan  
University of Medical Sciences

##### Expected recruitment start date

2017-05-22, 1396/03/01

##### Expected recruitment end date

2017-08-22, 1396/05/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of intravenous ketorolac versus intravenous morphine on pain relief in spinal traumatic patients: a double blind randomized controlled trial

##### Public title

Comparison of intravenous ketorolac versus intravenous morphine on pain relief in spinal traumatic patients

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Age of 15 to 66 years; spinal trauma.  
Exclusion criteria: Pregnancy or breastfeeding; narcotic and alcohol addiction; thoracic pain; hemorrhage; low consciousness; liver disease; communication disorders.

#### Age

From **15 years** old to **66 years** old

#### Gender

Both

#### Phase

2

#### Groups that have been masked

No information

#### Sample size

Target sample size: **100**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

Randomization: Random assignment of the patients to the intervention and control groups through drawing of lots. Blinding: Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Therefore, the trial will be run as double blind.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

##### Street address

Vice-chancellor for Research the Technology,  
Hamadan University of Medical Sciences, Shahid  
Fahmideh Ave

##### City

Hamadan

##### Postal code

6517838695

#### Approval date

2017-01-28, 1395/11/09

#### Ethics committee reference number

IR.UMSHA.REC.1395.492

## Health conditions studied

### 1

#### Description of health condition studied

Spinal trauma

#### ICD-10 code

T09.3

#### ICD-10 code description

Injury of spinal cord, level unspecified

## Primary outcomes

### 1

#### Description

Pain

#### Timepoint

before intervention and 5, 15, 30, 45 and 60 minutes  
after intervention

#### Method of measurement

using visual analog scale

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Infusion of ketorolac 30 mg in 100 normal saline for 15 minutes.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Infusion of morphine 1 mg/kg in in 100 normal saline for 15 minutes.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Besat Hospital

##### Full name of responsible person

Sajad Ghahramani

##### Street address

Besat Hospital, Shahed Square

##### City

Hamadan

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Vice-chancellor for Research and Technology,  
Hamadan University of Medical Sciences

**Full name of responsible person**

Dr Saeid Bashirian

**Street address**

Hamadan University of Medical Sciences, Shahid  
Fahmideh Ave

**City**

Hamadan

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice-chancellor for Research and Technology, Hamadan  
University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

**Person responsible for general inquiries****Contact****Name of organization / entity**

Besat Hospital

**Full name of responsible person**

Sajad Ghahramani

**Position**

Medical Student

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Besat Hospital, Shahed Square

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Heroboy1371@gmail.com

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Besat Hospital

**Full name of responsible person**

Dr Rasoul Salimi

**Position**

Emergency Medicine Specialist

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Department of Epidemiology

**Full name of responsible person**

Dr Jalal Poorolajal

**Position**

Associate Professor

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**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*