

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

### Comparison of the complications and pain relieving of nebulized morphine and intravenous morphine in trauma patients with musculoskeletal pain.

#### Protocol summary

##### Summary

The primary objective of this study is to compare the pain level and side effects of nebulized morphine with intravenous morphine in trauma patients referred for musculoskeletal pain. This study is a randomized clinical trial. Patients are not informed of the route of drug administration i.e. intravenous vs. nebulized. Patients are randomized to receive morphine sulfate for pain relief via any of the 3 aforementioned methods (0.1 mg / kg intravenous morphine or 0.2 mg / kg of nebulized morphine or 0.4 mg / kg of nebulized morphine). The Response to pain, and drug side effects are evaluated within designated time intervals of 0, 15, 30, and 45, 60-minute following the interventions by questionnaires. Inclusion criteria: Age: 18 and 65 years of age Acute and severe musculoskeletal pain between 6 and 10 on VAS. Exclusion criteria: Disinclined to participate in research projects; Drug addiction; Systolic blood pressure less than 90 mm Hg; GCS less than 15; Pregnancy and lactation; Known hypersensitivity to morphine and ketamine; Need for local nerve block; Incapable to understand the concept of VAS. Sample size: We enrolled 240 patients. We evaluated the response to pain relief, and the possible side effects of morphine in different dosage administered via intravenous vs. nebulized route in trauma patients with musculoskeletal pain. The primary outcome: Pain relief Secondary outcomes: Morphine side effects

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017011431931N1**

Registration date: **2017-06-13, 1396/03/23**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-06-13, 1396/03/23

##### Registrant information

###### Name

Ali Dashti

###### Name of organization / entity

Iran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 4462 6024

###### Email address

dashti.a@iums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Investigator

##### Expected recruitment start date

2017-02-19, 1395/12/01

##### 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 the complications and pain relieving of nebulized morphine and intravenous morphine in trauma patients with musculoskeletal pain.

##### Public title

The effect of morphine in reducing pain

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria were: age between 18 and 65 years; severe acute musculoskeletal pain between 6 and 10 on VAS. Exclusion criteria: Consent to participate in research projects; Drug addiction; Systolic blood pressure less than 90 mmHg; GCS less than 15; Heart, lung, kidney, liver or mental diseases; Pregnancy and lactation; Known hypersensitivity to morphine and ketamine.

**Age**

From **18 years** old to **65 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **240**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Single blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics committee of Iran University of Medical Sciences

**Street address**

Iran University of Medical Sciences Besides Milad Tower, Hemmat Highway

**City**

Tehran

**Postal code****Approval date**

2015-11-15, 1394/08/24

**Ethics committee reference number**

IR.IUMS.REC 1395.9411307014

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

pain

**ICD-10 code**

R52.0

**ICD-10 code description**

Acute pain

**Primary outcomes****1****Description**

Pain

**Timepoint**

0, 15, 30, 45 and 60 minutes after intervention

**Method of measurement**

Questionnaire

**Secondary outcomes****1****Description**

Hypotension

**Timepoint**

0, 15, 30, 45 and 60 minutes after intervention

**Method of measurement**

Blood pressure cuff

**2****Description**

Apnea

**Timepoint**

0, 15, 30, 45, and 60 minutes after intervention

**Method of measurement**

puls oximetry

**3****Description**

Oxygen saturation

**Timepoint**

0, 15, 30, 45, and 60 minutes after intervention

**Method of measurement**

puls oximetry

**4****Description**

Nausea and vomiting

**Timepoint**

0, 15, 30, 45 and 60 minutes after intervention

**Method of measurement**

Observation

**Intervention groups****1****Description**

Intervention group 1: 1.0 mg/kg of diluted morphine will be administered intravenously and 5 cc of sterile water will be given via nebulizer as placebo. Pain and drug side

effects will be evaluated 0, 15, 30, 45, and 60-minute after drug administration and if the pain isn't relieved, another 5 mg intravenous Morphine sulfate will be given.

**Category**

Treatment - Drugs

**2****Description**

Intervention group 2: 2.0 mg/kg of nebulized morphine sulfate is administered via facemask, and 5 cc of sterile water is given via nebulizer as placebo. Pain and drug side effects will be evaluated 0, 15, 30, 45, and 60-minute after drug administration and if the pain isn't relieved, 5 mg intravenous Morphine sulfate will be given.

**Category**

Treatment - Drugs

**3****Description**

Intervention group 3: 4.0 mg/kg of nebulized morphine sulfate is administered via facemask and 5 cc of sterile water is given via nebulizer as placebo. Pain and drug side effects will be evaluated 0, 15, 30, 45, and 60-minute after drug administration and if the pain isn't relieved, 5 mg intravenous Morphine sulfate will be given.

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Rasoul Akram Hospital

**Full name of responsible person**

Dr.Mani mofidi, Dr.Ali Dashti

**Street address**

Rasoul Akram Hospital, Shahr Ara avenue, Niayesh avenue, Sattarkhan street

**City**

Tehran

**2****Recruitment center****Name of recruitment center**

Firoozgar Hospital

**Full name of responsible person**

Dr. Ali Dashti

**Street address**

Firoozgar Hospital, Valiasr blvd. Valiasr Sq. Tehran

**City**

Tehran

**3****Recruitment center****Name of recruitment center**

Hafta Tir Hospital

**Full name of responsible person**

Dr. Ali Dashti

**Street address**

Hafta Tir Hospital, Rajaie St. Shahre Rey. Tehran

**City**

Shahre Rey

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Research Assistant

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Iran University of Medical Sciences, Besides Milad Tower, Hemmat Highway

**City**

Tehran

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

Yes

**Title of funding source**

Iran 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**

Iran University of Medical Sciences

**Full name of responsible person**

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**Position**

Resident of Emergency Medicine

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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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*