

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)

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+98 21 4462 6024

Email address

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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

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

Firoozgar Hospital

Full name of responsible person

Dr. Ali Dashti

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Firoozgar Hospital, Valiasr blvd. Valiasr Sq. Tehran

City

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

Hafta Tir Hospital

Full name of responsible person

Dr. Ali Dashti

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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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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

Dr. Ali Dashti

Position

Resident of Emergency Medicine

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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