Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

Comparison of analgesic effects and morphine consumption of intravenous morphine sulfate and intranasal dexmedetomidine with intravenous morphine sulfate in patients with extremity fractures presented in emergency departments

Protocol summary

Study aim

Comparison of analgesic effects and morphine consumption of intravenous morphine sulfate and intranasal dexmedetomidine with intravenous morphine sulfate in patients with extremity fractures presented in emergency department

Design

The design of the study is a randomized clinical trial. The randomization method is blocked. The sample size for each study group is 30.

Settings and conduct

In this research, all patients referred to the Emergency Department of Shohada-e- Haftome tir , Hazrat Rasoul Akram and Firouzgar Hospital, who suffered from extremity fractures will be enrolled. Patients will be randomly divided into two groups based on 10 blocks. A total of 60 patients will be examined. Patients and data analyzers will be blind.

Participants/Inclusion and exclusion criteria

All patients referred to the Emergency Department of Shohada-e- Haftome tir , Hazrat Rasoul Akram and Firouzgar Hospital, who suffered from extremity fractures will be enrolled. Inclusion criteria: Organ trauma leading to acute fractures, Patients over the eighteen years old. Exclusion criteria: Loss of consciousness, Chronic kidney and coronary artery disease, Pregnancy, Drinking alcohol and drugs.

Intervention groups

In intervention group, Patients will receive intravenous morphine sulfate at a dose of 5 mg plus intranasal dexmedetomidine 10 mg per kg of body weight. In control group, Patients will receive morphine at a dose of 5 mg plus a nasal placebo that will be distilled water.

Main outcome variables

Severity of pain after prescribing, Total dosage of the drug.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111114008104N15**
Registration date: **2019-01-02, 1397/10/12**
Registration timing: **prospective**

Last update: **2019-01-02, 1397/10/12**
Update count: **0**

Registration date

2019-01-02, 1397/10/12

Registrant information

Name

Mohammad Amin Zare

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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ma-zare@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-05, 1397/10/15

Expected recruitment end date

2019-05-05, 1398/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of analgesic effects and morphine consumption of intravenous morphine sulfate and intranasal dexmedetomidine with intravenous morphine sulfate in patients with extremity fractures presented in emergency departments

Public title
Effect of intravenous morphine sulfate and intranasal dexmedetomidine on Patients' Pain

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Organ trauma leading to acute fractures Patients over the eighteen years old
Exclusion criteria:
Loss of consciousness Chronic kidney and coronary artery disease Pregnancy Drinking alcohol and drugs

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be randomly assigned to two groups. In order to randomize, a random block method will be used. For this purpose, we formed blocks with 10 person. In each block, 5 individuals will be in intervention group and 5 will be in control group. A total of 6 blocks will be considered for sample size.

Blinding (investigator's opinion)
Double blinded

Blinding description
Data will analyze by person who is blind to study groups, and patients will also be unaware of the type of treatment.

Placebo
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, Hemmat Highway, Tehran
City
Tehran
Province
Tehran
Postal code
1449614535

Approval date
2017-07-26, 1396/05/04

Ethics committee reference number
IR.IUMS.REC.1397.566

Health conditions studied

1

Description of health condition studied
extremity fracture

ICD-10 code
M84.4

ICD-10 code description
Pathological fracture, not elsewhere classified

Primary outcomes

1

Description
Severity of pain after prescribing

Timepoint
After 15, 30, 60 and 120 minutes after using the drug

Method of measurement
From 1 to 10 (Based on numerical scale).

2

Description
Total dosage of the drug

Timepoint
After the end of treatment

Method of measurement
Based on the information in the patient file

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients will receive intravenous morphine sulfate at a dose of 5 mg plus intranasal

dexmedetomidine 10 mg per kg of body weight.

Category

Treatment - Drugs

2

Description

Control group: Patients will receive morphine at a dose of 5 mg plus a nasal placebo that will be distilled water.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Rasoul Akram hospital

Full name of responsible person

Mohammad Amin Zare

Street address

Emergency department, Hazrate Rasool hospital, Niyayesh street, Sattarkhan

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2

Recruitment center

Name of recruitment center

Firouzgar hospital

Full name of responsible person

Mohammad Amin Zare

Street address

Vali Asr Sq. Beh Afarin Ave.

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3

Recruitment center

Name of recruitment center

Shohada-e- Haftome tir Hospital

Full name of responsible person

Mohammad Amin Zare

Street address

Emergency Department, Shohada-e- Haftome tir Hospital, Shahid rajaee Highway, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Kazem Malakooti

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Mohammad Amin Zare

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

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Person responsible for scientific inquiries

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Position

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Latest degree

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Person responsible for updating data

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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

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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