

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Comparison of analgesic effects of intravenous morphine sulfate and intranasal dexmedetomidine with alone intravenous morphine sulfate in opoids consumer patients with extremity fractures presented in emergency departments of Shohadaye 7-Tir ,hezrate rasool & firoozgar hospitals

#### Protocol summary

##### Study aim

The purpose of the study is to compare the effect of intravenous morphine with nasal dexmedetomidine and morphine on pain intensity and morphine intake in drug abuse patients with extremity fracture referring Emergency

##### Design

The study design is a randomized clinical trial. The randomization method is block type. The sample size for each study group is 30 persons.

##### Settings and conduct

In this study, all patients referred to the Emergency Department of Haft-e-Tir , Hazrat Rasool and Firoozgar Hospital, who have extremity fractures, will be enrolled in the study. Patients will be randomly divided into two groups based on 10 blocks. A total of 60 patients will be evaluated. Patients and information analysts will be blind.

##### Participants/Inclusion and exclusion criteria

All patients referred to the Emergency Department of Haft-e-Tir , Hazrat Rasool and Firoozgar Hospital with extremity fractures will be enrolled. Inclusion criteria: Limb trauma leading to acute fractures, patients over 18 years. Exclusion criteria: Decreased consciousness, chronic renal and cardiovascular disease, pregnancy, alcohol use and psychotropic drugs.

##### Intervention groups

In the intervention group, patients received 5 mg morphine plus Dexmedetomidine is one tenth of a milligram per kilogram of body weight Will receive. In control group, patients received 5 mg morphine plus nasal placebo which will be distilled water.

##### Main outcome variables

Severity of pain after administration, total dose

#### General information

##### Reason for update

##### Acronym

Iran Ems Study

##### IRCT registration information

IRCT registration number: **IRCT20190608043839N1**

Registration date: **2020-05-26, 1399/03/06**

Registration timing: **prospective**

Last update: **2020-05-26, 1399/03/06**

Update count: **0**

##### Registration date

2020-05-26, 1399/03/06

##### Registrant information

##### Name

Ahmad Vafajoo

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 4244 1527

##### Email address

dr.vafajoo@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-06-21, 1399/04/01

##### Expected recruitment end date

2020-10-22, 1399/08/01

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of analgesic effects of intravenous morphine sulfate and intranasal dexmedetomidine with alone intravenous morphine sulfate in opoids consumer patients with extremity fractures presented in emergency departments of Shohadaye 7-Tir ,hezrate rasool & firoozgar hospitals

**Public title**

Effects of intravenous morphine sulfate and intranasal dexmedetomidine in extremity fractures patients

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Opoids consumer Acute extremity fracture Age Above 18 years old

**Exclusion criteria:**

Low of consciounesses Chronic renal failure Cirrhosis Pregnancy Alcohol use Heart & vascular disease Psychotropic drugs use

**Age**

From **18 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients will be randomly divided into two groups. in order to Randomization The block randomization method will be used. For this purpose 10 blocks will be formed and 5 blocks per block In the intervention group and 5 people in the control group. Overall 6 blocks will be considered to reach the sample size.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The information will be analyzed by a person who does not know the study groups. Patients will be unaware of the treatment.

**Placebo**

Used

**Assignment**

Parallel

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

empty

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

Ethics Committee of Medical School Research - Iran University of Medical Sciences

**Street address**

Block A, 13th Floor, Iran Sime St. - Headquarters of Ministry of Health and Medical Education, Between South Flamak and Zarafshan, Qods Town (West)

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۴۳۹۶۱۴۵۳۵

**Approval date**

2019-09-24, 1398/07/02

**Ethics committee reference number**

IR.IUMS.FMD.REC.1398.300

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

Extremity fractures

**ICD-10 code**

M84.4

**ICD-10 code description**

Pathological fracture, not elsewhere classified

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

Severity of pain after drug administration

**Timepoint**

After 15, 30, 60 and 120 minutes after drug administration

**Method of measurement**

Visual Numerical Rating Scale

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

Total dosage of the drug

**Timepoint**

After the end of treatment

**Method of measurement**

Based on the information in the patient file

## Intervention groups

### 1

#### Description

Intervention group: Patients will receive morphine at a dose of 5 mg plus dexmedetomidine 1.5 mg / kg.

#### 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 Rasool Akram Hospital

##### Full name of responsible person

Ahmad Vafajoo

##### Street address

Emergency Department of Hazrat Rasoul Hospital Complex, Niayesh Ave., Sattarkhan, Iran

##### City

Tehran

##### Province

Tehran

##### Postal code

1445613131

##### Phone

+98 21 6435 2190

##### Fax

+98 21 6435 2190

##### Email

ir.ac.iums@hrmc

##### Web page address

<http://hrmc.iums.ac.ir/>

### 2

#### Recruitment center

##### Name of recruitment center

Firoozgar Hospital

##### Full name of responsible person

Ahmad Vafajoo

##### Street address

Street to Afar, Vali Asr Square

##### City

Tehran

##### Province

Tehran

##### Postal code

1593747811

##### Phone

+98 21 8214 1600

##### Fax

+98 21 8214 1600

##### Email

com.yahoo@firoozgar\_h

##### Web page address

<http://firoozgar.iums.ac.ir/>

### 3

#### Recruitment center

##### Name of recruitment center

7th Tir Martyrs Hospital

##### Full name of responsible person

Ahmad Vafajoo

##### Street address

Shahid Rajaiei Highway, Emergency Department, Haft-e Tir Hospital

##### City

Tehran

##### Province

Tehran

##### Postal code

1886718136

##### Phone

+98 21 5522 8580

##### Fax

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##### Email

ir.ac.iums@web7tir

##### Web page address

<http://hosph.t.iums.ac.ir/>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Kazem Malekoti

##### Street address

Iran University of Medical Sciences, Hemmat Highway, Tehran, Iran

##### City

Tehran

##### Province

Tehran

##### Postal code

1445613131

##### Phone

+98 21 8670 2503

##### Email

ir.ac.iums@research

##### 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

**Street address**

Sattarkhan Street, Nayayesh Street, Rasoul Akram Hospital, Ward Emergency

**City**

Tehran

**Province**

Tehran

**Postal code**

1445613131

**Phone**

+98 21 8670 2503

**Email**

com.yahoo@mazare74

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

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**Position**

assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Emergency Medicine

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Mohammad Amin Zare

**Position**

assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Emergency Medicine

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**Province**

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**Postal code**

1445613131

**Phone**

+98 21 8670 2503

**Email**

mazare74@yahoo.com

**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