

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

+98 21 5522 8580

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

Mohammad Amin Zare

Position

assistant 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 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

Street address

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

City

Tehran

Province

Tehran

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