

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Effect of nebulized Fentanyl in relief pain due to acute limb trauma and comparing it with intravenous Morphine sulfate.

Protocol summary

Summary

The main goal of this study is finding and recommending of new method for relieving pain and delivery of drugs. Ninety Patients, who were referred to Emergency department of Imam Khomeini Hospital in clinical shifts of researcher, were complaining pain due to acute limb trauma and included for trial, received one of two randomized drug packs. Patients who had these conditions included to trial: pain with severity index more than 5 of 10 with Numerical Pain Score (NRS); was not in special groups (pregnancy and breast feeding); their health condition was in group one of American Society of Anesthesiology (ASA); had not any chronic use of analgesics and had no addiction (alcohol, opium ...). Intervention group received intravenous Distilled water as placebo in one minute then nebulized Fentanyl within 5 minutes. Control group received intravenous Morphine sulfate in one minute then nebulized Distilled water as placebo within 5 minutes. Patients in both groups asked and monitored for changes in severity of pain as primary outcome and secondary outcomes such as change in cardiac rhythm, level of consciousness, blood pressure, arterial oxygen saturation, respiratory rate and pulse rate. Results documented in 5, 10, 15, 30 and 60 minutes after receiving drugs. Patients who had insufficient response to treatment of pain at time 15 were receiving rescue dose of intravenous Morphine sulfate at times 15 and 30. At the end patients asked for global satisfaction of this method.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012111710585N1**

Registration date: **2013-03-20, 1391/12/30**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-03-20, 1391/12/30

Registrant information

Name

Saeed Shiralizadeh

Name of organization / entity

Tehran University of Medical Science

Country

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Recruitment status

Recruitment complete

Funding source

By personal resources and University finance

Expected recruitment start date

2012-11-19, 1391/08/29

Expected recruitment end date

2012-12-20, 1391/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of nebulized Fentanyl in relief pain due to acute limb trauma and comparing it with intravenous Morphine sulfate.

Public title

Intravenous Morphine sulfate versus nebulized Fentanyl in patients with acute pain.

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria: all patients who presented to our ED and were complaining pain due to acute limb trauma with severity index of pain at least 5 of 10 in Numerical Pain Score (NRS). Exclusion criteria: special group of patients (pregnant, breast feeding); history of respiratory disease such as asthma; patients who were receiving neuroleptic drugs; patients with chronic pain, opium or alcohol addiction or chronic use of analgesics.

Age
From **16 years** old to **50 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description

Placebo
Used

Assignment
Single

Other design features
In this study we had two similar packages of drugs that had prepared with study headmaster. Both of them included two 10 milliliter syringes that had filled with clear liquid by headmaster of study; Patients randomly treated with one of the packages that randomized by 4 digits block manner. Our study is triple blind because researcher, patients and analyzer of results did not know anything about contents of each package.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Science

Street address

Room 501, floor 5, Central building of Tehran University of Medical Science

City

Tehran

Postal code

Approval date

2012-10-11, 1391/07/20

Ethics committee reference number

91/D/130/1602

Health conditions studied

1

Description of health condition studied

Acute limb trauma

ICD-10 code

S40, S41,

ICD-10 code description

Superficial injury to shoulder and upper arm, Open wound of shoulder and upper arm, fracture of shoulder and upper arm, Dislocation, sprain and strain of joints and ligaments of shoulder girdle, Superficial injury of forearm, Open wound of forearm, Fractu

Primary outcomes

1

Description

Pain score which is reported by patient.

Timepoint

Five, 10, 15, 30 and 60 minutes after receiving drugs.

Method of measurement

Questionnaire by Numerical Pain Scale(NRS)

Secondary outcomes

1

Description

Respiratory rate.

Timepoint

Five, 10, 15, 30, 60 minutes after receiving drugs.

Method of measurement

Questionnaire

2

Description

Patient's Global rating of satisfaction

Timepoint

One hour after receiving drug via nebulizer

Method of measurement

Questionnaire

3

Description

The period of time between treatment and the onset of analgesia.

Timepoint

Five, 10, 15, 30, 60 minutes after receiving drugs.

Method of measurement

Questionnaire

4

Description

Total dose of rescue dose of Morphine sulfate.

Timepoint

Since 15 minutes after receiving drug via nebulizer

Method of measurement

milligram

5**Description**

The percentage of arterial Oxygen saturation.

Timepoint

Five, 10, 15, 30, 60 minutes after receiving drugs.

Method of measurement

Percent

6**Description**

Systolic and diastolic blood pressure.

Timepoint

Five, 10, 15, 30, 60 minutes after receiving drugs.

Method of measurement

millimeter of mercury

7**Description**

Heart rate.

Timepoint

Five, 10, 15, 30, 60 minutes after receiving drugs.

Method of measurement

Beat per minute

8**Description**

Level of consciousness.

Timepoint

Five, 10, 15, 30, 60 minutes after receiving drugs.

Method of measurement

Questionnaire

9**Description**

The number of reported nausea or vomiting.

Timepoint

Five, 10, 15, 30, 60 minutes after receiving drugs.

Method of measurement

Questionnaire

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

In group 1 or intervention group patients received drug and placebo in 2 syringes that were filled by study headmaster. Both of the syringes contained 10 milliliter of clear liquid. Syringe number 1 contained 10 milliliters distilled water as placebo for intravenous injection by dose of 0.1 milliliter/kilogram of body weight within 1 minute. Syringe number 2 contained 10 milliliter of 50 Micro gram/milliliter of Fentanyl that build in Iranian drug industry (Daroupakhsh or Abureihan). Fentanyl prescribed via nebulizer by dose of 0.08

milliliter/kilogram equal to dose of four Micro gram/Kilogram within 5 minutes after intravenous drug. Patients had been monitored for change in pain scale by 10 number Numerical Pain Score (NRS) and side effects in 5, 10, 15, 30 and 60 minutes after receiving drug via nebulizer by asking them with a questionnaire. Patients who had not reported decrease in pain scale at least 3 number, 15 minutes after nebulized drug, received 1 milligram rescue dose of morphine sulfate intravenously at times 15 and 30 minutes after nebulized drug.

Category

Treatment - Drugs

2**Description**

In group 2 or control group patients received drugs in 2 syringes that were filled by study headmaster and both of them contained 10 milliliters of clear liquid. Syringe number 1 contains 10 milliliters of morphine sulfate; build in Iranian drug industry (Daroupakhsh or Abureihan) that diluted to 1 milligram/milliliter for intravenous injection. Intra venous Morphine sulfate prescribed by dose of 0.1 milliliter/kilogram equal to 0.1 milligram/kilogram of body weight within 1 minute. Syringe number 2 contains 10 milliliter of distilled water as placebo for prescription via nebulizer by dose of 0.08 milliliter/kilogram within 5 minutes after intravenous drug. Patients had been monitored for change in pain scale by 10 number Numerical Pain Score (NRS) and side effects in 5, 10, 15, 30 and 60 minutes after receiving drug via nebulizer by asking them via questionnaire. Patients who had not reported decrease in pain scale at least 3 number, 15 minutes after drugs, received 1 milligram rescue dose of Morphine sulfate intravenously.

Category

Treatment - Drugs

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

Emergency department of Imam Khomeini Hospital;
Tehran University of Medical Science

Full name of responsible person

Dr Shervin Farahmand; Dr Saeed Shiralizadeh

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Emergency Department of Imam Khomeini Hospital,
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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

The vice chancellor for research, The medical school
of Tehran University of Medical Science

Full name of responsible person

Dr. shahin akhondzadeh

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The vice chancellor for research, room 206, floor 1,
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City

Tehran

Grant name

پایان نامه رزیدنتی

Grant code / Reference number

19858/210/d/89

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

The vice chancellor for research, The medical school of
Tehran University of Medical Science

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**

Tehran University of Medical Science

Full name of responsible person

Dr. Shervin Farahmand

Position

Assistance professor of emergency medicine

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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