

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

The effect of inhalation and intravenous fentanyl on pain severity of patients with limb fracture

Protocol summary

Summary

Objective: assessment the effect of inhalation and intravenous fentanyl on pain severity of patients with upper or lower limbs fracture. Design: double blind clinical trial Setting and conduct: pain severity will assess in 5, 10, 15, 30 and 60 minutes in both groups. Participants including major eligibility criteria: this study will conduct on 212 patients with trauma in Ahvaz Imam and Golestan hospitals. Main inclusion criteria age range of 15 to 55 years and having upper and lower limbs fracture and main exclusion criteria include using of antisycotic, sedative, tricyclic antidepressant, selective serotonin reuptake inhibitor, monoamine oxidase inhibitor drugs; having allergy and fentanyl contraindication. Patients will allocate to two equal groups of inhalation and intravenous fentanyl according to table of random numbers. Intervention: patients in intravenous fentanyl group will receive 1 µgr/kg intravenous fentanyl of 50 µgr/ml solution and 5 ml normal saline via inhalation. Patients in inhalation fentanyl group will receive 5 ml intravenous normal saline and 4 µgr/kg fentanyl of 50 µgr/ml solution in combination with 5 ml normal saline via inhalation. Main outcome measures (variables): pain severity

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015082423748N1**
Registration date: **2016-04-30, 1395/02/11**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-04-30, 1395/02/11

Registrant information

Name

Ala Bahrami

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 3554 8975

Email address

bahrami.a@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Ahvaz Judishapur University of Medical Sciences

Expected recruitment start date

2015-08-23, 1394/06/01

Expected recruitment end date

2016-06-20, 1395/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of inhalation and intravenous fentanyl on pain severity of patients with limb fracture

Public title

Comparison the effect of inhalation and intravenous fentanyl on pain severity of patients with upper or lower limbs fracture

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: age range of 15 to 55 years; having upper and lower limbs fracture. Exclusion criteria: using

of antisyctic, sedative, tricyclic antidepressant, selective serotonin reuptake inhibitor, monoamine oxidase inhibitor drugs; having addiction to drugs or opioids; having acute and chronic renal diseases, liver and heart diseases, respiratory diseases (upper and lower respiratory system infection, asthma, chronic obstructive pulmonary diseases); having allergy; being pregnant; fentanyl contraindication.

Age

From **15 years** old to **55 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **212**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Ahwaz Jundishapur University of Medical Sciences

Street address

Ahwaz Jundishapur University of Medical Sciences, Golestan road, Ahwaz, Khozestan

City

Ahwaz

Postal code

15794-61357

Approval date

2015-06-06, 1394/03/16

Ethics committee reference number

IR.AJUMS.REC.1394.136

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

pain in limb

ICD-10 code

M79.6

ICD-10 code description

pain in limb

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

Pain severity

Timepoint

5 , 10 , 15, 30 and 60 minutes

Method of measurement

Visual analogue scale

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

Pain severity of lower limb

Timepoint

5, 10, 15, 30 and 60 minutes

Method of measurement

Visual analogue scale

2**Description**

Pain severity of upper limb

Timepoint

5, 10, 15, 30 and 60 minutes

Method of measurement

Visual analogue scale

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

Patients in intervention group will receive 1 µgr/kg intravenous fentanyl of 50 µgr/ml solution and 5 ml normal saline via inhalation.

Category

Treatment - Drugs

2**Description**

Patients in control group will receive 5 ml intravenous normal saline and 4 µgr/kg fentanyl of 50 µgr/ml solution in combination with 5 ml normal saline via inhalation.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center**

Name of recruitment center

Golestan hospital

Full name of responsible person

Mohammadreza Malaki Varaki

Street address

Golestan hospital, Golestan road, Ahvaz, Khozestan

City

Ahvaz

2

Recruitment center

Name of recruitment center

Emam Khomeini hospital

Full name of responsible person

Mohammadreza Malaki Varaki

Street address

Emam Khomeini hospital, Ahvaz, Khozestan

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Ahvaz Judishapur University of Medical Sciences

Full name of responsible person

Mohammadreza Malaki Varaki

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Ahvaz Jundishapur University of Medical Sciences, Golestan road, Ahvaz, Khozestan

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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

Vice chancellor for research, Ahvaz Judishapur 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

Ahvaz Judishapur University of Medical Sciences

Full name of responsible person

Mohammadreza Malaki Varaki

Position

Emergency medicine

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

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Position

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Other areas of specialty/work

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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