

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 Gholesan 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: **IRCT2015111425027N1**
Registration date: **2016-05-11, 1395/02/22**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-05-11, 1395/02/22

Registrant information

Name

Mohammadreza Maleki Varaki

Name of organization / entity

Ahvaz Judishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 3374 3079

Email address

maleki-m@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 antipsychotic, 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

N/A

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, Ahvaz, Khozestan

City

ahvaz

Postal code

15794-61357

Approval date

2014-05-27, 1393/03/06

Ethics committee reference number

IR.AJUMS.REC.1394.136

Health conditions studied

1

Description of health condition studied

pain

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

empty

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, Ahwaz Judishapur
University of Medical Sciences

Full name of responsible person
Mohamadreza Malaki Varaki

Street address
Ahwaz Jundishapur University of Medical Sciences,
Golestan road, Ahvaz, Khozestan

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ahvaz

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, Ahwaz 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
Ahwaz 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

Contact

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Position
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Other areas of specialty/work

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Email
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Web page address

Person responsible for updating data

Contact

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