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 Gholestan 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, Ahwaz 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 antisycotic, 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
Ahvaz 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
Ahvaz Jundishapur University of Medical Sciences, Golestan road, Ahvaz, Khozestan
City
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
Street address
Golestan hospital, Golestan road, Ahvaz, Khozestan
City
ahvaz
Postal code
Phone
+98 912 278 2787
Fax
Email
Drmalaki676@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Ahvaz Judishapur University of Medical Sciences
Full name of responsible person
Mohamadreza Malaki Varaki
Position
Emergency medicine
Other areas of specialty/work
Street address
Golestan hospital, Golestan road, Ahvaz, Khozestan
City
ahvaz
Postal code
Phone
+98 912 278 2787
Fax
Email
Drmalaki676@yahoo.com
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