

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

the comparison of the effect of nebulizer of fentanyl and intravenous morphine in controlling the pain of patients with fracture of long bone

Protocol summary

Study aim

the comparison of the effect of nebulizer of fentanyl and intravenous morphine in controlling the pain of patients with fracture of long bone referring to Ayatollah Moosavi hospital in Zanjan

Design

Clinical trial with control group, with parallel groups, not-blinded, randomization, Phase 1-2 on 240 patients. Block randomization will be used.

Settings and conduct

the location of the study will be at Ayatollah Moosavi in Zanjan city. the intervention group will take fentanyl through nebulizer for five minutes. the control group will take intravenous Morphine Sulfate for one minute. in both groups, patients will be observed in terms of pain severity as the main monitored outcome and under cardiac monitoring, pulse oximetry, consistent control of respiratory rate, pulse rate, and the level of consciousness and the results will be recorded in the fifth, tenth, fifteenth, thirtieth and sixtieth minute. in case of nonresponsiveness to treatment in the fifteenth minute, the saving dose of intravenous Morphine Sulfate at fifteenth and thirtieth minutes.

Participants/Inclusion and exclusion criteria

inclusion criteria: all patients referring to emergency with a complaint of pain of acute trauma of limb with pain severity more than 5 based on 10-digit scale age between 20 to 50 years exclusion criteria: pregnancy and lactation, patients with multiple myeloma, patients with respiratory disorders like asthma ..., patients under treatment with neurological medications, drug and alcohol addiction, patient with chronic pain and long time consumption of analgesic medications

Intervention groups

the intervention group will take nebulizer of fentanyl during five minutes

Main outcome variables

pain severity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191109045385N1**

Registration date: **2020-05-20, 1399/02/31**

Registration timing: **retrospective**

Last update: **2020-05-20, 1399/02/31**

Update count: **0**

Registration date

2020-05-20, 1399/02/31

Registrant information

Name

Sarvenaz Salahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4424 2647

Email address

salahi13639@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-22, 1397/03/01

Expected recruitment end date

2019-05-22, 1398/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

the comparison of the effect of nebulizer of fentanyl and intravenous morphine in controlling the pain of patients with fracture of long bone

Public title

the comparison of pain controlling effect of nebulizer of fentanyl and intravenous morphine

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

patients aged 20-50 years Referring to emergency department the complaint of pain of acute trauma of limb the pain severity more than 5 based on 10-digit scale of pain

Exclusion criteria:**Age**

From **20 years** old to **50 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **240**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple individual randomization using a table of random numbers. Each of the eligible persons is given a numeric code. Then, each number selected by the computer is placed in the intervention group. After selecting 120 individuals as the intervention group, the remaining individuals are considered as the control group.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Zanjan University of medical sciences

Street address

Zanjan province, Zanjan, Gavazang Boulevard

City

Zanjan

Province

Zanjan

Postal code

4513956183

Approval date

2019-06-21, 1398/03/31

Ethics committee reference number

IR.ZUMS.REC.1398.072

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

fracture of long bone

ICD-10 code

G89.11

ICD-10 code description

Acute pain due to trauma

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

pain severity

Timepoint

at the fifth, tenth , fifteenth , thirtieth and sixtieth minute after starting consumption of nebulizer of fentanyl in intervention group and consumption of intravenous Morphine Sulfate

Method of measurement

10-digit apin scale

Secondary outcomes

empty

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

Intervention group: will take the nebulizer of fentanyl during five minutes

Category

Treatment - Drugs

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

Ayatollah Moosavi hospital

Full name of responsible person

غلامرضا حمیدخلق

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Zanjan University of Medical Sciences
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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

Zanjan 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
Zanjan University of Medical Sciences
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Mohsen Salehi
Position
Assistant professor
Latest degree
Specialist
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Email

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

there is no other information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available