

# 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

**Street address**

Zanjan province , Zanjan , Gavazang Boulevard

**City**

Zanjan

**Province**

Zanjan

**Postal code**  
4513956183  
**Phone**  
+98 24 3313 0000  
**Email**  
salahi13639@gmail.com

**City**  
Zanjan  
**Province**  
Zanjan  
**Postal code**  
4513956183  
**Phone**  
+98 24 3313 0000  
**Email**  
m.salehi@zums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Zanjan University of Medical Sciences  
**Full name of responsible person**  
Mohsen Salehi  
**Street address**  
Zanjan province, Zanjan, Gavazang Boulevard  
**City**  
Zanjan  
**Province**  
Zanjan  
**Postal code**  
4513956183  
**Phone**  
+98 24 3313 0000  
**Email**  
Mousavihospital@zums.ac.ir  
**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  
**Full name of responsible person**  
Mohsen Salehi  
**Position**  
Assistant professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Emergency Medicine  
**Street address**  
Zanjan province , Zanjan, Gavazang Boulevard

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Zanjan University of Medical Sciences  
**Full name of responsible person**  
Mohsen Salehi  
**Position**  
Assistant professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Emergency Medicine  
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Zanjan  
**Province**  
Zanjan  
**Postal code**  
4513956183  
**Phone**  
+98 24 3313 0000  
**Email**  
m.salehi@zums.ac.ir

## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Zanjan University of Medical Sciences  
**Full name of responsible person**  
غلامرضا حمید خلق  
**Position**  
رزیذنت  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Emergency Medicine  
**Street address**  
Zanjan province , Zanjan, Gavazang Boulevard  
**City**  
Zanjan  
**Province**  
Zanjan  
**Postal code**  
4513956183  
**Phone**  
+98 24 3313 0000  
**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