

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

Comparison of analgesic effect of Morphine versus Fentanyl in isolated closed femor fracture in trauma patients

Protocol summary

Summary

This study is a single blind randomized clinical trial to compare the effects on pain and morphine, fentanyl pain in patients with femoral shaft fractures were admitted to the emergency. Inclusion criteria: patients with femur fractures, one-sided, single and classification of 1 or 2 ASA; patients 18 to 55 years of both sexes; a maximum of 20 minutes after arrival to the emergency department trauma. Exclusion criteria were: decreased level of consciousness (GCS less than 14) and neural tube defects (FND); respiratory depression, hypotension (systolic blood pressure <90) and generally patients with hemodynamically unstable; multiple trauma (injury to intra-abdominal organs, bleeding Notably, head trauma); Tyad to drugs. Patients in group 1 (35 patients receiving 1.0 mg kg intravenous morphine sulfate with distilled water to a final volume reached 10 ml) and group 2 (35 patients, 5.1 mg kg group receiving fentanyl intravenous (12)) are. Two groups of patients before and after injection (0), 15 minutes and 30 minutes after treatment by visual analogue scale (Visual Analog Scale- VAS) are evaluated, as well as possible side effects and vital signs (blood pressure systolic and diastolic, heart rate and respiratory rate, body temperature) and arterial oxygen saturation, as well as in patients by Czech list has been prepared for this purpose, is recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016053028171N1**

Registration date: **2016-09-18, 1395/06/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-09-18, 1395/06/28

Registrant information

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Name of organization / entity

Arak University of Medical Sceinces

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor University of Medical Sciences

Expected recruitment start date

2014-10-15, 1393/07/23

Expected recruitment end date

2016-03-13, 1394/12/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of analgesic effect of Morphine versus Fentanyl in isolated closed femor fracture in trauma patients

Public title

Comparison of analgesic effect of Morphine versus Fentanyl in isolated closed femor fracture in trauma patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with femur fractures, one-sided, single and classification of 1 or 2 ASA; patients 18 to 55 years of both sexes; a maximum of 20 minutes after arrival to the emergency department trauma. Exclusion criteria were: decreased level of consciousness (GCS less than 14) and neural tube defects (FND); respiratory depression, hypotension (systolic blood pressure <90) and generally patients with hemodynamically unstable; multiple trauma (injury to intra-abdominal organs, bleeding Notably, head trauma); Tyad to drugs.

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single 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 Arak University of Medical Sciences

Street address

St. Alamolhoda, St. Maskan, Arak

City

Arak

Postal code

Approval date

2014-10-15, 1393/07/23

Ethics committee reference number

22-169-93

Health conditions studied

1

Description of health condition studied

femor fracture

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Systolic blood pressure

Timepoint

Before and after injection (0), 15 minutes and 30 minutes after taking drugs.

Method of measurement

Sphygmomanometer

2

Description

Diastolic blood pressure

Timepoint

Before and after injection (0), 15 minutes and 30 minutes after taking drugs.

Method of measurement

Sphygmomanometer

Secondary outcomes

1

Description

heart beat

Timepoint

Before and after injection (0), 15 minutes and 30 minutes after taking drugs.

Method of measurement

ECG

Intervention groups

1

Description

Intervention group 1: 35 patients receiving 1.0 mg kg intravenous morphine sulfate that has been distilled water to a final volume of 10 ml.

Category

Treatment - Drugs

2

Description

Intervention group 2: 35 patients in the group receiving 5.1 micrograms per kilogram of Fentanyl are.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Valiasr Hospital Arak
Full name of responsible person
Dr. tabatabaei Mohsen
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Person responsible for scientific inquiries

Contact

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for research Arak University of Medical Sciences
Full name of responsible person
Dr. Mohammad Rafiee
Street address
Arak, School of Medicine
City
Arak
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 Arak 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
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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