

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jun 2026

Comparison of Intravenous Morphine with Fentanyl Transdermal Patches on pain intensity of Patients with Fracture of Tibia

Protocol summary

Study aim

Comparison of the effect of intravenous morphine and fentanyl skin patch on pain intensity of patients with shank bone fracture

Design

Clinical trials with community based and pragmatic control group, with parallel groups, one blind, randomized

Settings and conduct

Clinical and one-blind clinical anesthesia study on patients referred to the emergency department of Valiasr Hospital in Arak city with leg fracture.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 18 years old; fracture of the leg
Exclusion criteria: Failure to detect fractures in radiography photos; Background of underlying diseases

Intervention groups

Case group (n=60) : Fentanyl patch in the same areas (left deltoid muscle, right deltoid muscle, left and right chest at the top of the nipple after shivering) Control group (n=60) : Received 0.1 mg / kg vial of morphine

Main outcome variables

pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150808023552N15**

Registration date: **2018-05-04, 1397/02/14**

Registration timing: **retrospective**

Last update: **2018-05-04, 1397/02/14**

Update count: **0**

Registration date

2018-05-04, 1397/02/14

Registrant information

Name

Abolfazl Jokar

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

dr.a.jokar@gmail.com

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research , Arak University of Medical Sciences

Expected recruitment start date

2016-11-21, 1395/09/01

Expected recruitment end date

2017-05-22, 1396/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Intravenous Morphine with Fentanyl Transdermal Patches on pain intensity of Patients with Fracture of Tibia

Public title

Effect of intravenous morphine with fentanyl skin patch on shin bone fracture

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Fracture of Tibia Aged 18 years and older

Exclusion criteria:

Failure to detect fractures in radiographic images
Background of underlying diseases

Age

From **18 years** old to **90 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Not accidental

Blinding (investigator's opinion)

Single blinded

Blinding description

Analyzer Blind

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

Arak, Rahahan Street

City

Arak

Province

Markazi

Postal code

3819838453

Approval date

2015-09-23, 1394/07/01

Ethics committee reference number

lr.arakmu.rec.1395.139

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

Fracture of Tibia

ICD-10 code

S82.2

ICD-10 code description

Fracture of tibia

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

severity of pain

Timepoint

Every 20 minutes 2 hours after the first administration of morphine, or fentanyl skin patch

Method of measurement

VAS ruler

Secondary outcomes

empty

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

Intervention group: Fentanyl patch is affixed in the same area and is fastened by a person

Category

Treatment - Other

2**Description**

Control group: received morphine 0.1mcg / kg intravenously

Category

Treatment - Other

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

Arak Vali Asr Hospital

Full name of responsible person

Dr. Abolfazl Jokar

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Arak, Valiasr Square, Valiasr Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr. Mohammad Rafiee

Street address

Arak, Sardasht, School of Medicine

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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

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Dr. Abolfazl Jokar

Position

Emergency Medicine Specialist

Latest degree

Specialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Information on the main consequence of sharing is

possible
When the data will become available and for how long
Start the access period 6 months after printing the results
To whom data/document is available
For scholars working in academia and academia
Under which criteria data/document could be used
researchers
From where data/document is obtainable
Author
What processes are involved for a request to access data/document
Once the author agrees, the online data will be available online
Comments