Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 Sceinces
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Iran (Islamic Republic of)
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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
Ir.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

Street address
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
Emergency Medicine

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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