Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison the effectiveness of enoxaparin subcutaneous injection duration on the severity of injection pain in hospitalized patients in orthopedics ward

Protocol summary

Summary

This study will be done with the aim to investigate the effectiveness of enoxaparin subcutaneous injection duration on the severity of injection pain in hospitalized patients in orthopedics ward. This study is a single blind clinical trial. The study population will be consisted of patients referred to orthopedic wards of Taleghani Hospital of Kermanshah city. A total of 182 persons will be selected in available method and randomly will be assigned into two interventional groups. In the first group first injection will be done in the 10 seconds in left or right side of the abdomen to a distance of 5 cm from the navel and the second injection will be done after 24 hours on the other side of the abdomen within 30 seconds. In the second group first injection will be done in the 30 seconds in left or right side of the abdomen to a distance of 5 cm from the navel and the second injection will be done after 24 hours on the other side of the abdomen to a distance of 5 cm from the navel within 10 seconds with a pre-filled syringe with a volumes 6 ml of enoxaparin with injection of 2 ml air without any aspiration. After each injection by waterproof pen a circular is drawn around the area with a diameter of 5 cm. Inclusion criteria: Age between 80-18 years; Conscious patients and able to understand the expression of pain; Do not receive any painkiller for 4 hours prior to the intervention. Exclusion criteria: Coagulation disorder or requires another drug subcutaneous injection in the abdominal area during intervention

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016112614333N62**

Registration date: **2017-02-18, 1395/11/30**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-02-18, 1395/11/30

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1821 4653

Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kermanshah University of Medical Sciences

Expected recruitment start date

2017-02-13, 1395/11/25

Expected recruitment end date

2017-04-04, 1396/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effectiveness of enoxaparin subcutaneous injection duration on the severity of

injection pain in hospitalized patients in orthopedics ward

Public title
The effectiveness of enoxaparin subcutaneous injection duration on the severity of injection pain in hospitalized patients in orthopedics ward
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Age between 80-18 years; Conscious patients and able to understand the expression of pain; Do not receive any painkiller for 4 hours prior to the intervention. Exclusion criteria: Death of patient; Coagulation disorder or requires another drug subcutaneous injection in the abdominal area during intervention
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **182**
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 Kermanshah University of Medical Sciences
Street address
Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences
City
Kermanshah
Postal code
Approval date
2017-01-11, 1395/10/22
Ethics committee reference number
kums.rec.1395.599

Health conditions studied

1

Description of health condition studied
pain
ICD-10 code
s82.1
ICD-10 code description
fracture of upper end of tibia , fracture of shaft of tibia , fracture of lower end of tibia

Primary outcomes

1

Description
Pain intensity
Timepoint
Immediately after injection
Method of measurement
Based on the scoring based on the use of NRS

Secondary outcomes

empty

Intervention groups

1

Description
In the first group first injection will be done in the 10 seconds in left or right side of the abdomen to a distance of 5 cm from the navel and the other injection will be done after 24 hours on the other side of the abdomen within 30 seconds
Category
Treatment - Drugs

2

Description
In the second group first injection will be done in the 30 seconds in left or right side of the abdomen to a distance of 5 cm from the navel and the second injection will be done after 24 hours on the other side of the abdomen to a distance of 5 cm from the navel within 10 seconds.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleghani Hospital
Full name of responsible person
Mohammad Moradian
Street address
Taleghani Hospital, Shahid Beheshtir Boulevard

City
Kermanshah

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Kermanshah University of Medical Sciences
Full name of responsible person
Koroush Hamzehee
Street address
Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences
City
Kermanshah
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, Kermanshah 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

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Ahmad Khoshay
Position
Master of Science in Nursing
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Person responsible for updating data

Contact
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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