

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 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

fforoughi@kums.ac.ir

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 18-80 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 Beheshtiir 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

Other areas of specialty/work

Street address

School of Nursing & Midwifery, Dolatabad Boulevard, Eisar Square

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+98 83 3826 6429

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akhoshay@yahoo.com

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Person responsible for updating data

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Mohammad Moradian

Position

Critical Care Nursing Graduate Student

Other areas of specialty/work

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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