

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

The effect of local cold application and injection duration, on the occurrence of bruising and pain at the injection site in subcutaneous enoxaparin sodium injections

Protocol summary

Summary

The purpose of this study is to determine and compare the effect of local cold application and injection duration on occurrence of pain and bruising injection site in patients whom receive subcutaneous enoxaparin sodium injections . Subcutaneous administration of enoxaparin is a common nursing intervention. Heparin preparations are widely used for post-surgical prophylaxis, deep vein thrombosis and pulmonary emboli. This subcutaneous injection often causes problem such as bruise and pain at site of injection. This problem may lead to anxiety and disruption of body image and refuse of treatment in patients. 72 patients who receive enoxaparin will be divided into four groups. Each group consist of 18 patients. First group receive 10 second injection duration (routine method of injections); second group: cold apply to injection site for 5 minute before10 second injection duration; third group: 10 second injection duration and waiting 10 second before exit needle; fourth group: cold apply for 5 minute before10 second injection duration and waiting10 seconds before exit needle. Following each injection, the patient pain intensity will be measured immediately by visual analogue scale. The site of bruising will be measured at 24, 48, and 72 hours after each injection by a plastic ruler.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201201158731N1**

Registration date: **2012-08-14, 1391/05/24**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-08-14, 1391/05/24

Registrant information

Name

Hossein Rahmani_anaraki

Name of organization / entity

Golestan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 17 1442 6900

Email address

rahmani@goums.ac.ir

Recruitment status

Recruitment complete

Funding source

Golestan university of medical sciences

Expected recruitment start date

2012-05-04, 1391/02/15

Expected recruitment end date

2012-08-08, 1391/05/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of local cold application and injection duration, on the occurrence of bruising and pain at the injection site in subcutaneous enoxaparin sodium injections

Public title

The effect of local cold application and injection duration on the occurrence of bruising and pain at the injection site in subcutaneous enoxaparin sodium injections

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: patient who receives subcutaneous injection of 60mg anoxaparine twice a day as treatment program; not to have coagulation disorders; not to have other injection in abdomen site; enable to express pain of injection; not to use analgesic medication four hours before injection; upper 18 and lower 65 years old; to have written approval. Exclusion criteria: patients who have abnormal coagulation; any change anoxaparine doses; have any other injections at the abdominal site except anoxaparine during the days of the research.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **72**

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

Golestan university of medical sciences

Street address

kilometer 2 of Gorgan-Sari road

City

Gorgan

Postal code

49341-74515

Approval date

2012-05-22, 1391/03/02

Ethics committee reference number

533/35/پ گ

Health conditions studied

1

Description of health condition studied

skin and subcutaneous injury

ICD-10 code

L99

ICD-10 code description

Other disorders of skin and subcutaneous tissue in diseases classified elsewhere

Primary outcomes

1

Description

pain

Timepoint

immediately

Method of measurement

visual analog scale

2

Description

skin bruise

Timepoint

24, 48, and 72 hours later

Method of measurement

millimeter

Secondary outcomes

empty

Intervention groups

1

Description

first group: routine method of injection, subcutaneous anoxaparine (10 second duration injection technique)

Category

Prevention

2

Description

second group: cold apply to injection site for 5 minute before, 10 second injection duration

Category

Prevention

3

Description

third group: 10 second injection duration and waiting 10 second before exit needle

Category

Prevention

4

Description

fourth group: cold apply for 5 minute before 10 second injection duration and waiting 10 seconds before exit needle.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

5th Azar Educational and Medical Center

Full name of responsible person

Street address

5Azar street, Gorgan

City

Gorgan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Golestan university of medical sciences

Full name of responsible person

Dr. Mohsen Aarabi

Street address

kilometer 2 Gorgan-Sari road

City

Gorgan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Golestan 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

Golestan university of medical sciences

Full name of responsible person

Hossein Rahmani anaraki

Position

academic instructor

Other areas of specialty/work

Street address

Golestan university of medical sciences

City

Gorgan

Postal code

Phone

+98 17 1442 6900

Fax

Email

rahmani@goums.ac.ir ; rahmani_anaraki@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Golestan university of medical sciences

Full name of responsible person

Hossein Rahmani anaraki

Position

academic instructor

Other areas of specialty/work

Street address

Golestan university of medical sciences

City

Gorgan

Postal code

Phone

+98 17 1442 6900

Fax

Email

rahmani@goums.ac.ir ; rahmani_anaraki@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Golestan university of medical sciences

Full name of responsible person

Hossein Rahmani anaraki

Position

academic instructor

Other areas of specialty/work

Street address

Golestan university of medical sciences

City

Gorgan

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Phone

+98 17 1442 6900

Fax

Email

Web page address

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