Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Nov 2026

Study of effect of subcutaneous enoxaparin sodium injection duration on incidence and extent of bruising at injection site in hospitalized patient.

Protocol summary

Summary

This single blind crossover clinical trial aims to determine the effect of subcutaneous enoxaparin sodium injection duration on incidence and extent of bruising at injection site in patients admitted to intensive coronary care units in Heshmat hospital in Rasht. 122 samples will be selected by randomized block sampling method with inclusion criteria of patients being in the first 24 hours of hospitalization in cardiac care unit who need to remain hospitalized for at least another 48 hours; coagulation tests results within therapeutic range; written order for subcutaneous enoxaparin sodium 6000 IU in patients`record; no special treatments required (fibrinolytic therapy,...), widespread skin lesions on the right side of the abdomen or any blood and liver diseases and signing written consent form to participate in the study. Exclusion criteria includes any changes in drug order or dosage, discharge before data gathering time duration and death of a patient . Samples will be randomly allocated in two groups of A (n=56) with injection method 1 (10 seconds on the right upper abdomen) on first day and method 2 (20 seconds injection right lower abdomen) on the second day and group B (n=56) with method 2 on the first day and method 1 on second day. All injections will be performed by the researcher in the morning shifts using pre-filled enoxaparin sodium 6000 IU, prepared by Alborzdarou company, and a stopwatch to measure the time. The incidence of bruising and its extent will be evaluated by a colleague in 48 hours after each injection using a flexible ruler.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2015032721547N1**
Registration date: **2015-06-14, 1394/03/24**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-06-14, 1394/03/24

Registrant information

Name

Shirin Jafroudi

Name of organization / entity

Shahid Beheshti Nursing and Midwifery College

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Social determinants of Health research Center, Gilan University of medical sciences, Rasht , Iran

Expected recruitment start date

2015-05-15, 1394/02/25

Expected recruitment end date

2015-07-23, 1394/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of effect of subcutaneous enoxaparin sodium injection duration on incidence and extent of bruising at injection site in hospitalized patient.

Public title
Study of effect of subcutaneous enoxaparin sodium injection duration on incidence and extent of bruising at injection site in hospitalized patients.
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: Patients being in the first 24 hours of hospitalization in cardiac care unit who need to remain hospitalized for at least another 48 hours; coagulation tests results within therapeutic range; written order for subcutaneous 6000 IU enoxaparin sodium in patients`record; no special treatments required (fibrinolytic therapy, angioplasty,...), widespread skin lesions on the right side of the abdomen or any blood and liver diseases and signing written consent form to participate in the study. Exclusion criteria: Any changes in drug order or dosage, discharge before data selection time duration and death of a patient .
Age
From **18 years** old to **90 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **112**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Guilan University of Medical Sciences
Street address
Eastern Shahid Beheshti Boulvard, Vice Chancellor for research of Guilan University of Medical Sciences
City
Rasht
Postal code
Approval date
2015-03-17, 1393/12/26
Ethics committee reference number
2930003523

Health conditions studied

1

Description of health condition studied
Bruising in site of enixaparin sodium injection
ICD-10 code
T81.0
ICD-10 code description
Hemorrhage in any site resulting from a procedure

Primary outcomes

1

Description
The incidence of bruising in site of enoxaparin sodium injection
Timepoint
48 hours after intervention
Method of measurement
Recording the observed bruising in prepared form

2

Description
The extent of bruising in area of Enoxaparin sodium in Milimeter
Timepoint
48 hours after intervention
Method of measurement
Recording the bruising extent (by flexible ruler in milimeter) in prepared form

Secondary outcomes

empty

Intervention groups

1

Description
Group A: Samples(n=56) will receive pre-filled syring of enoxaparin sodium 6000 IU (prepared by Alborzdarou company), subcutaneously in two sequence days and in two methods of 1 (drug injection in 10 seconds in the right upper quadrant of abdomen) at first day and 2 (injection for 20 seconds including drug injection in 10 seconds and waiting for10 seconds more before needle withdrawal in the right lower quadrant of abdomen) at second day (24 hours apart). Drug injection method and patient teaching content will be the same as group B, except its duration. A stopwatch will use to control the exact time.The Injected area will circled about 5 cm diameter by a waterproof pen by naming 1 for the method 1 and 2 for method 2. A trained researcher fellow without any knowledge about the groups and injection method will evaluate the injected sites for bruises incidence and extent in about 48 hours after

each injection by a flexible ruler in mm.

Category

Prevention

2

Description

Group B: Samples(n=56) will receive pre-filled syring of enoxaparin sodium 6000 IU (prepared by Alborzdarou company), subcutaneously in two sequence days and in two methods of 2 (injection for 20 seconds including drug injection in 10 seconds and waiting for10 seconds more before needle withdrawal in the right lower quadrant of abdomen) at first day and method 1 (drug injection) in 10 seconds in the right upper quadrant of abdomen) at second day (24 hours apart). Drug injection method and patient teaching content will be the same as group A, except its duration. A stopwatch will use to control the exact time.The injected area will circled about 5 cm diameter by a waterproof pen by naming 1 for the method 1 and 2 for method 2. A trained researcher fellow without any knowledge about the group and injection method will evaluate the injected sites for bruises incidence and extent 48 hours after each injection by a flexible ruler in mm.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Heshmat educational therapeutic center

Full name of responsible person

Shirin Jafroudi

Street address

Heshmat educational therapeutic center, Beheshti Boulvard.

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Social determinants of health research center, Guilan university of medical sciences, Rasht, Iran

Full name of responsible person

Shirin Jafroudi

Street address

Social determinants of health research center, Beheshti nursing and midwifery college, Daneshjoo street, Western Beheshti Boulevard

City

Rasht

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Social determinants of health research center, Guilan university of medical sciences, Rasht, Iran

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

Beheshti nursing and midwifery college, Guilan university of medical sciences

Full name of responsible person

Shirin Jafroudi

Position

Master of science in nursing, medical and surgical nursing teaching

Other areas of specialty/work

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Person responsible for updating data

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Other areas of specialty/work
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s-jafroudi@gums.ac.ir
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