

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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

+98 13 3355 5058

Email address

s_jafroudi@gums.ac.ir

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 Boulevard, 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 enoxaparin 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 Millimeter

Timepoint

48 hours after intervention

Method of measurement

Recording the bruising extent (by flexible ruler in millimeter) 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 for 10 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 Boulevard.

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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Beheshti college, Guilan university of medical sciences

Full name of responsible person

Shirin Jafroudi

Position

Master science of nursing, instructor, faculty member

Other areas of specialty/work**Street address**

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City**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*