Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of local cold and warmth upon the size of bruising at the injection site of subcutaneous Enoxaparin.

Protocol summary

Summary

This study is for comparing the effect of local cold and warmth upon the size of bruising at the injection site of subcutaneous Enoxaparin. It will be conducted in general cardiology department of Emam-Ali hospital in Kermanshah. One-hundred and eighty patients who are above 18years old, who do not be pregnant, has not any coagulation disorders and receive Enoxaparin 60mg two times in a day, will randomly assign to 3 groups through choosing a pocket involved the name of control group or the name of experimental groups. In the experimental group-1: cold compress will be used for patients immediately after administration of Enoxaparin for 20 minutes on injection site. In the experimental group-2: cold compress will be used for them immediately after administration of Enoxaparin for 20 minutes on injection site, then 12hours after that warm compress will be put on the injection site too, and the third group is control group. Injection-site bruising will measured at 24, 48 and 72 hours after each injection by cooperator who don't know the patient's group through a millimeter ruler. If there is not any bruising, it is recorded and if there is, the biggest diameter of it measured and recorded. The bruising with size more 5 millimeter will be called as large bruising and with size between 2-5 millimeter will be called as small one. The bruising with size less 2 millimeter, will not be called as bruising. Then sizes of bruising will be compared during 3 days for all participant.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014040917197N1**
Registration date: **2014-05-23, 1393/03/02**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2014-05-23, 1393/03/02

Registrant information

Name
Sara Amanian
Name of organization / entity
Nursing and Midwifery School of Tehran University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 83 1724 9584
Email address
s-amaniyan@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2014-04-21, 1393/02/01

Expected recruitment end date

2014-06-22, 1393/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of local cold and warmth upon the size of bruising at the injection site of subcutaneous Enoxaparin.

Public title

Comparison of the effect of local cold and warmth upon the size of bruising at the injection site of subcutaneous

Enoxaparin.

Purpose

Prevention

Inclusion/Exclusion criteria

The patient do not be pregnant; has not any coagulation disorders; the patient has the written order for injection Enoxaparin 60mg by doctor per 12 hours; and there is not record of previous injections during last 24hours in his/her abdominal area. Exclusion criteria: The drug of Enoxaparin stopped by doctor or changed; there is bleeding in injection area.

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **180**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran university of Medical Sciences

Street address

The Central Building of Tehran university of Medical Scienc, keshavarz Street, Qods Street, Tehran, Iran

City

Tehran

Postal code

Approval date

2014-02-03, 1392/11/14

Ethics committee reference number

2597/130/92/د

Health conditions studied

1

Description of health condition studied

Diseases of skin and subcutaneouse tissue

ICD-10 code

XII

ICD-10 code description

L00-L99

Primary outcomes

1

Description

The size of bruising at the injection site of subcutaneous Enoxaparin.

Timepoint

Until 3 days after the injection

Method of measurement

Using a plastic ruler

Secondary outcomes

empty

Intervention groups

1

Description

In the group 1: cold compress are exerted on the injection site of 60 patients under treatment by subcutaneous Enoxaparin (60 mg), for 20 minutes, using a towel, just after every injection in abdomen.

Category

Prevention

2

Description

In the group 2: in addition to exertion of cold compress on the injection site of 60 patients under treatment by subcutaneous Enoxaparin (60 mg), for 20 minutes just after every injection in abdomen, over 12 hours of injection time, warm compress bag will be placed as well on the same point of injection, using a towel, for 20 minutes.

Category

Prevention

3

Description

Third group is called control group and dose not take any special action to these patients except routine injection of subcutaneous Enoxaparin.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

General Cardiology Ddepartments of Emem-Ali

hospital in Kermanshah

Full name of responsible person

Street address

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran Universiy of Medical Sciences

Full name of responsible person

Masood Younesian

Street address

The central building of Tehran university of Medical Sciences, Qods Street, Keshavarz Street, Tehran, Iran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran Universiy 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

The faculty of Nursing and Midwifery of Tehran University of Medical Scienses

Full name of responsible person

Shokooh Varaie

Position

PHD

Other areas of specialty/work

Street address

The faculty of Nursing and Midwifery of Tehran University of Medical Scienses, Nosrat Street, Tohid Squre, Tehran, Iran

City

Tehran

Postal code

Phone

+98 21 6105 4327

Fax

Email

shvaraei@tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

The Faculty of Nursing and Midwifery of Tehran University of Medical Scienses

Full name of responsible person

Sara Amanian

Position

Master Sciences Student of Nursing

Other areas of specialty/work

Street address

The Faculty of Nursing and Midwifery of Tehran University of Medical Scienses, Nosrat Street, Tohid Square, Tehran, Iran

City

Tehran

Postal code

Phone

+98 83 1724 9191

Fax

+98 83 1724 8439

Email

amanian51@yahoo.com; daneshfar1987@yahoo.com

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