

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Effect of implementing local cooling in different times versus no implementation on pain severity and extend of bruise due to subcutaneous enoxaparin injection in cardiovascular patients: a randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of implementing local cooling in different times versus no implementation on pain severity and extend of bruise due to subcutaneous enoxaparin injection in cardiovascular patients Design: a randomized clinical trial. Setting and conduct: The eligible cardiovascular patients who will refer to Farshchian Hospital during the study period will be enrolled into the trial. Inclusion criteria: (a) age of 30 to 70 years; (b) indication of subcutaneous enoxaparin injection for the first time; (c) conscious and ability to percept and state the pain. Exclusion criteria: (a) receiving analgesic within past 4 hours; (b) death or discharge during 72 hours; (c) coagulopathy; (d) using anticoagulant agents. Intervention group: (a) local cooling using ice bag for 180 seconds 5 minutes before subcutaneous enoxaparin injection; (b) local cooling using ice bag for 180 seconds immediately after subcutaneous enoxaparin injection. Control group: Subcutaneous enoxaparin injection without any intervention. Primary outcome: Measuring pain severity using visual analog scale immediately after injection. Secondary outcome: Measuring extend of bruise using ruler 12, 24, and 48 hours after injection. Randomization: The patients will be randomly assigned to intervention and control groups using random number table. Blinding: Not possible.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201602029014N92**
Registration date: **2016-02-11, 1394/11/22**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-02-11, 1394/11/22

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan
University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research the Technology, Hamadan
University of Medical Sciences

Expected recruitment start date

2016-02-20, 1394/12/01

Expected recruitment end date

2016-07-22, 1395/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of implementing local cooling in different times versus no implementation on pain severity and extend of bruise due to subcutaneous enoxaparin injection in

cardiovascular patients: a randomized clinical trial

Public title

Effect of implementing local cooling in different times versus no implementation on pain severity and extend of bruise due to subcutaneous enoxaparin injection in cardiovascular patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: (a) age of 30 to 70 years; (b) indication of subcutaneous enoxaparin injection for the first time; (c) conscious and ability to percept and state the pain. Exclusion criteria: (a) receiving analgesic within past 4 hours; (b) death or discharge during 72 hours; (c) coagulopathy; (d) using anticoagulant agents.

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization: The patients will be randomly assigned to intervention and control groups using random number table. Blinding: Not possible.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research the Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

Postal code

6517838695

Approval date

2016-01-23, 1394/11/03

Ethics committee reference number

IR.UMSHA.REC.1394.441

Health conditions studied

1

Description of health condition studied

Pain

ICD-10 code

R52.9

ICD-10 code description

Pain, unspecified

Primary outcomes

1

Description

Measuring pain severity

Timepoint

immediately after injection

Method of measurement

using visual analog scale

Secondary outcomes

1

Description

Measuring extend of bruise

Timepoint

12, 24, and 48 hours after injection

Method of measurement

using ruler

Intervention groups

1

Description

ocal cooling using ice bag for 180 seconds 5 minutes
before subcutaneous enoxaparin injection

Category

Prevention

2

Description

local cooling using ice bag for 180 seconds immediately
after subcutaneous enoxaparin injection

Category

Prevention

3

Description

Subcutaneous enoxaparin injection without any
intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Farshchian Hospital

Full name of responsible person

Mostafa Najafi

Street address

Farshchian Hospital, Shahid Fahmideh Ave.

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research the Technology,
Hamadan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

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Hamadan University of Medical Sciences, Shahid
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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 the Technology, Hamadan
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

Farshchian Hospital

Full name of responsible person

Mostafa Najafi

Position

Nursing Student

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Nursing Trainer

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Department of Epidemiology

Full name of responsible person

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Associate Professor

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