

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of the cold pack on bruising and pain caused by subcutaneous injection of enoxaparin sodium on elderly patients

Protocol summary

Study aim

Determine the effect of the cold pack on bruising and pain caused by subcutaneous injection of Enoxaparin in the elderly

Design

Each patient in the interventional group constituted his or her own control group. In this study, simple randomization was used. In the case of patients whose last digit of their ID number are odd, the left side of the abdomen are the interventional group and the right side of the abdomen are control group, and if they are paired, their right side of abdomen will be the interventional group and the left side of the of the abdomen are control group.

Settings and conduct

Elderly patients with a MMSE ≥ 25 and receiving enoxaparin, are block randomization assigned to the right and left abdomen to the control and intervention groups. In the intervention group, for 2 minutes, the cold pack was placed before and after injection in the area, and the severity of the pain during the injection is measured by the visual analogue scale and in the case of bruising, the injection area is 24, 48 and 72 hours after injection with a ruler Millimeters are measured. In the control group, all procedures, except cold pack, will be performed in the same way as the intervention group.

Participants/Inclusion and exclusion criteria

Receiving Enoxaparin; Awareness Based on a MMSE; Being hospitalized at least 3 days; Having informed consent; Lack of injecting medication or other anticoagulants in the abdomen; Not having cold skin allergy; Normal PT, PTT, INR and platelets

Intervention groups

In the abdominal intervention area, the cold pack is placed for 2 minutes before and after the injection

Main outcome variables

The pain score during enoxaparin injection according Visual Analogue Scale, and so bruising size in 24, 48 and 72 hours after enoxaparin injection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160606028289N2**

Registration date: **2018-12-17, 1397/09/26**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-17, 1397/09/26**

Update count: **0**

Registration date

2018-12-17, 1397/09/26

Registrant information

Name

Mohammad Esmaeilpour-Bandboni

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13565071

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m_esmaeilpour@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-22, 1397/09/01

Expected recruitment end date

2019-01-21, 1397/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of the cold pack on bruising and pain caused by subcutaneous injection of enoxaparin sodium on elderly patients

Public title

The effect of cold pack on the complications of enoxaparin injection

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Receiving enoxaparin Being aware according MMSE
Being hospitalized at least for 3 days Having informed consent Non-injecting drug or other anticoagulant in the abdomen wall Not having cold skin allergy Normal PT, PTT, INR and platelets

Exclusion criteria:

Discharge earlier than 3 days Skin allergy to the cold pack during intervention Reluctance to continue cooperation Bleeding from the injection site Decreased consciousness in the study process

Age

From **60 years** old to **90 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **88**
More than 1 sample in each individual
Number of samples in each individual: **2**
Subcutaneous injection of Enoxaparin with and without the use of a cold pack on the right and left abdomen of each participant.

Randomization (investigator's opinion)

Randomized

Randomization description

Each patient in the interventional group constituted his or her own control group. In this study, simple randomization was used. In the case of patients whose last digit of their ID number are odd, the left side of the abdomen are the interventional group and the right side of the abdomen are control group, and if they are paired, their right side of abdomen will be the interventional group and the left side of the of the abdomen are control group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee of Guilan University of Medical Sciences

Street address

Vice-Chancellor in Research Affairs of Guilan University of Medical Sciences., facing of 17 Shahrivar Hospital., Shahid Siadati St., Namjoo Street., Rasht

City

Rasht

Province

Guilan

Postal code

4144666949

Approval date

2018-10-09, 1397/07/17

Ethics committee reference number

IR.GUMS.REC.1397.258

Health conditions studied

1

Description of health condition studied

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The complications of Enoxaparin injection

Timepoint

During, 24, 48 and 72 hours after injection

Method of measurement

The using of the Visual Analogue Scale and Transparent millimeter ruler

Secondary outcomes

1

Description

The Score of the patients' pain

Timepoint

The measurement of pain during injection

Method of measurement

According to Visual Analogue Scale

2

Description

The measurement of Bruising size

Timepoint

24, 48 and 72 hours after Enoxaparin injection

Method of measurement

Transparent millimeter ruler

Intervention groups

1

Description

Intervention group: Elderly patients with a MMSE ≥ 25 and receiving enoxaparin, are randomly assigned to the right and left abdomen to the control and intervention groups. In the intervention group, for 2 minutes, the cold pack was placed before and after injection in the area, and the severity of the pain during the injection is measured by the visual analogue scale and in the case of bruising, the injection area is 24, 48 and 72 hours after injection with a ruler Millimeters are measured. In the control group, all procedures, except cold pack, will be performed in the same way as the intervention group.

Category

N/A

2

Description

Control group: In the control group, all procedures, except using a cold pack, will be performed in the same way as the intervention group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Lahijan 22 Aban hospital

Full name of responsible person

Mohammad Esmaeilpour-Bandboni

Street address

Lahijan 22 Aban hospital., Lahijan, Imam Khomeini St

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Dr Shadman Nemati

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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

Rasht University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Mohammad Esmaeilpour-Bandboni

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

No - There is not a plan to make this available