Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 2026

Assessing the effect of applying local cold and hot pack on the bruising extent of Enoxaparin sodium injection site in patients admitted

Protocol summary

Study aim

determine the effect of topical cold and heat on bruises induced by subcutaneous injection of enoxaparin sodium in patients admitted to the orthopedic ward of Poursina Hospital in Rasht.

Design

This study is a single randomized controlled clinical trial by parallel group.The samples size is 74. At first, the samples are selected by convenience sampling method. Then, allocated in the intervention group 1 and intervention group 2 .

Settings and conduct

the study is conducted in patients admitted to the orthopedic ward of Poursina Hospital in Rasht.In intervention group 1 (local cold) after administration of enoxaparin sodium, a cold pack is applied at a place of injection for 20 minutes. In the intervention group 2 (local cold-heat), in addition to the cold pack for 20 minutes, 24 hours later, the warm pack for 20 minutes is applied.The bruising extent is measured by a researcher fellow with ruler for up to 3 days at 24, 48, 72 hours after injection in both groups.

Participants/Inclusion and exclusion criteria

The inclusion criteria:attendance in the first 24 h of admission ; requiring hospital admission for at least 72 h after receiving the second injection in the left abdomen; enoxaparin sodium ordering (6000 u) normal coagulation,renal function,Hct & Plt tests ; No lesions on the abdomen. exclusion criteria :any change in the clinical condition is required changing in the amount or discontinuation of the drug, injection in right side by personel & unwillingness to continue cooperation.

Intervention groups

In intervention group 1 (local cold) after administration of enoxaparin sodium, a cold pack is applied at a place of injection for 20 minutes . In the intervention group 2 (local cold-heat), in addition to the cold pack for 20 minutes, 24 hours later, the warm pack for 20 minutes is applied.

Main outcome variables

The extent of bruising in area of Enoxaparin sodium in Milimeter

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180623040206N1**
Registration date: **2018-07-17, 1397/04/26**
Registration timing: **registered_while_recruiting**

Last update: **2018-07-17, 1397/04/26**
Update count: **0**

Registration date

2018-07-17, 1397/04/26

Registrant information

Name

ataollah asadi louyeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-10, 1397/04/19

Expected recruitment end date

2018-08-21, 1397/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing the effect of applying local cold and hot pack on the bruising extent of Enoxaparin sodium injection site in patients admitted

Public title

"Assessing the effect of applying local cold and hot pack on the bruising extent of Enoxaparin sodium injection site in patients admitted "

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

requiring hospital admission for at least 72 hours after receiving the second injection in the left abdomen treatment with Enoxaparin sodium with a dose of 6000 units having the results of the latest coagulation tests include INR, PTT, PT in the range of therapy (up to 1.5-2.5 as normal), normal amounts of platelets and hematocrit adequate renal function (creatinine 1.5-0.5 mg / dL) lack of extensive skin lesions on the abdomen such as extensive scarring due to surgery or burn lack of conditions preventing the correct implementation of the Enoxaparin injection method such as sever Ascites abdominal bruises from the previous injection satisfaction to participate in the research by signing a written consent

Exclusion criteria:

event of any change in the clinical condition is required changing in the amount or discontinuation of the drug performing subcutaneous injections Enoxaparin sodium on the right side of the abdomen by personnel unwillingness to continue cooperation

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **74**

Randomization (investigator's opinion)

Randomized

Randomization description

The samples size is 74. At first, the samples are selected by convenience sampling method and based on the inclusion criteria. Then, 37 subjects are allocated in the intervention group 1 (Local cold on the right side of the abdomen) and 37 in the intervention group 2 (Local cold-heat on the right side of the abdomen) based on the randomized blocking on a computer and obtaining a precise list in four block.

Blinding (investigator's opinion)

Single blinded

Blinding description

Data on bruising is gathering through observing injection site for bruising and measuring its breadth by using a transparent millimeter ruler by afellow trained researcher who does not know any information about injection methods

Placebo

Not used

Assignment

Parallel

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

Province

Guilan

Postal code

93345-41938

Approval date

2018-06-11, 1397/03/21

Ethics committee reference number

IR.GUMS.REC.1397.094

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 extent of bruising in area of Enoxaparin sodium in Milimeter

Timepoint

24,48 and 72 hours after intervention

Method of measurement

Recording the bruising extent based on multiplication of the largest diameter in the smallest diameter (by flexible ruler in millimeter) in prepared form.

2

Description

The incidence of bruising in site of Enoxaparin sodium injection:discoloration in skin to violet color at least 2 mm

Timepoint

24,48 and 72 hours after intervention

Method of measurement

Recording the observed bruising in prepared form by flexible ruler in millimeter)to measure skin discoloration

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1: Samples(n=37) will receive per-filled syringe of enoxaparin sodium 6000 IU (prepared by Alborzdarou company), subcutaneously after administration on the right of the abdomen,applying a cold pack at a place of injection for 20 minutes with a temperature of 15 to 18 ° C. . The injection area will be identifying circled about 2/5 cm diameter by a waterproof pen, and then providing the education to patient about non-manipulation, including the lack of massage, scratching or touching the injection site. I n general, the investigator inject in two times in each groups. The first injection on the right side of the abdomen is considered as an intervention and the second injection, which is performed 24 hours after the first injection on the left side of the abdomen, is considered as a control. There will be no intervention on the left side of the abdomen (as control). Data on bruising is gathering through observing injection site for bruising and measuring its breadth by using a transparent millimeter ruler by a fellow trained researcher who does not know any information about injection methods. The bruising extent is recorded in up to 3 days at 24, 48, 72 hours after injection (right and left side of the abdomen) in each groups and recorded in the data sheet.

Category

Prevention

2

Description

Intervention group2: Samples(n=37) will receive per-filled syringe of enoxaparin sodium 6000 IU (prepared by Alborzdarou company), subcutaneously after administration on the right of the abdomen,applying the cold pack for 20 minutes, 24 hours later, the warm pack with a temperature 40-43 ° C for 20 minutes is applied . The injection area will be identifying circled about 2/5 cm diameter by a waterproof pen, and then providing the education to patient about non-manipulation, including the lack of massage, scratching or touching the injection site. I n general, the investigator inject in two times in each groups. The first injection on the right side of the abdomen is considered as an intervention and the second injection, which is performed 24 hours after the first injection on the left side of the abdomen, is considered as a control. There will be no intervention on the left side of the abdomen (as control). Data on bruising is gathering through observing injection site for bruising and measuring its breadth by using a transparent millimeter ruler by a fellow trained researcher who does not know any information about injection methods. The bruising extent is recorded in up to 3 days at 24, 48, 72 hours after injection (right and left side of the abdomen) in each groups and recorded in the data sheet.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Poursina educational therapeutic center

Full name of responsible person

Ataollah asadi louyeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research and Technology Deputy of Guilan University of Medical Sciences.

Full name of responsible person

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
Research and Technology Deputy of Guilan 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
Guilan university of medical sciences,Beheshti nursing and midwifery college
Full name of responsible person
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Position
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Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Total of data is Shareable after unidentifiable the people.
When the data will become available and for how long
Start the access period 6 months after printing the results
To whom data/document is available
Only for researchers working in academic and scientific institutions
Under which criteria data/document could be used
Meta analysis
From where data/document is obtainable
Ataollah Asadi Louyeh Guilan University of Medical Sciences. Shahid Beheshti Nursing and Midwifery School of Rasht
What processes are involved for a request to access data/document
contact by email
Comments