Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

Effect of localized cold compress before and after subcutaneous injection of enoxaparin sodium on pain severity and injection site bruising

Protocol summary

Study aim

The aim of this study was to evaluate the effect of topical cold on bruising and pain intensity at the subcutaneous injection of sodium enoxaparin in patients

Design

This clinical trial was conductedon 100 patients in five groups.Patients in this study were divided into 5 treatment groups (4 experimental groups and 1 control group). The data was collected by a researcher-made checklist containing two parts of the individual characteristics, the severity of pain, and the measurement of bruising. The amount of bruise was measured 24,48 and 72 hours after injection using a clear ruler and pain intensity was also evaluated using the VAS immediately after each injection.

Settings and conduct

This study was carried out in five groups (one control group and four intervention groups) at the Ayatollah Rohani Hospital in 2015. The sampling process was conducted at the heart part of Babol's Rohani hospital

Participants/Inclusion and exclusion criteria

The inclusion criteria included all patients who were under the age of 65 and above the age of 18 years, not pregnancy during the study and breastfeeding, had no previous injection at the site for 12 hours prior to the test, were fully alert and able to indicate pain, and had no history of coagulation disease and a injectable dose of enoxaprine 6000 units) was the same for all specimens.

Intervention groups

In the control group, subcutaneous injection was performed according to the routine method, and in the intervention groups, local cold was applied 5 minutes before injection, 5 minutes before and after injection, 5 minutes after injection, 20 minutes after injection, 5 minutes before and 20 minutes after injection with 10-second time duration.

Main outcome variables

Reduction of pain and bruising

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180827040884N2**
Registration date: **2020-11-01, 1399/08/11**
Registration timing: **retrospective**

Last update: **2020-11-01, 1399/08/11**
Update count: **0**

Registration date

2020-11-01, 1399/08/11

Registrant information

Name

Fatemeh Taghlili

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3239 9079

Email address

fa_taghlili@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2014-12-22, 1393/10/01

Expected recruitment end date

2015-04-21, 1394/02/01

Actual recruitment start date

2014-12-22, 1393/10/01

Actual recruitment end date

2015-04-21, 1394/02/01

Trial completion date

2015-10-23, 1394/08/01

Scientific title

Effect of localized cold compress before and after subcutaneous injection of enoxaparin sodium on pain severity and injection site bruising

Public title
Effect of localized cold compress before and after subcutaneous injection of enoxaparin sodium on pain severity and injection site bruising
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Were under the age of 65 and above the age of 18 years Not pregnancy during the study and breastfeeding Had no previous injection at the site for 12 hours prior to the test Were fully alert and able to indicate pain Had no history of coagulation disease Injectable dose of enoxaprine 6000 units) was the same for all specimens
Exclusion criteria:
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **100**
Actual sample size reached: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
The sampling process was conducted at the heart part of Babol's Rohani hospital. To do so, the researcher first selected those patients who were prescribed Enoxaprine 6000 units daily in the ward, and then classified into five groups using the number lottery bed Method. Then, for each group, the desired treatment was carried out. It should be noted that the sampling process continued until the sample size was complete in each 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
Ethics Committee of Islamic Azad University of Babol
Street address
No. 6,Sobhan Apartment, 21 Golestan, Eastern Belt, Babol.
City
babol
Province
Mazandaran
Postal code
4715763561
Approval date
2015-04-21, 1394/02/01
Ethics committee reference number
1569505230001

Health conditions studied

1

Description of health condition studied
Pain and bruising after subcutaneous injection
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Pain number with Visual Analogue Scale (VAS)
Timepoint
Measurment of pain 5 minutes before intervention and 5 minutes and 20 minutes after intervention
Method of measurement
Visual Analogue Scale

2

Description
The amount of bruising
Timepoint
Measurment of the amount of bruising 5 minutes before intervention and 5 minutes and 20 minutes after intervention
Method of measurement
Calibrated ruler

Secondary outcomes

empty

Intervention groups

1

Description
Control group: In the control group, the injection method was performed without any intervention in line with the standard injection technique, so that the injection done in the right or left abdomen from 5 cm around the umbilicus to the sides and the absence of aspiration with 10 seconds duration and without any massage after injection
Category

Rehabilitation

2

Description
Intervention group: . In the first intervention group, cold compresses placed (water and ice bags) 5 minutes before the injection
Category
Rehabilitation

3

Description
Intervention group: In the second intervention group, cold compresses placed (water and ice bags) 20 minutes after the injection
Category
Rehabilitation

4

Description
Intervention group: In the third intervention group, cold compresses placed (water and ice bags) 5 minutes before and after the injection
Category
Prevention

5

Description
Intervention group: In the fourth intervention group, cold compresses placed (water and ice bags) 5 minutes before and 20 minutes after the injection
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Rohani Hospital
Full name of responsible person
Fatemeh taghlili
Street address
No.6, 21 Golestan, Eastern Belt, Babol
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Iman dadashi
Street address
گرجی آباد،دانشگاه آزاد اسلامی واحد بابل
City
Babol
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4715763561
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+98 11 3241 5061
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info@baboliau.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Islamic Azad University
Proportion provided by this source
100
Public or private sector
Private
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
Islamic Azad University
Full name of responsible person
فاطمه تقلیلی
Position
Faculty member
Latest degree
Master
Other areas of specialty/work
Nursery
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
No more information

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
After the study has been completed and the results of the intervention have been obtained, the impact of the intervention will be published as a paper and will be available to interested parties.

When the data will become available and for how long
Start the access period 6 months after publishing

To whom data/document is available
Health and medical professionals

Under which criteria data/document could be used
Only the information results will be provided to those specializing in the field. Statistical information will be limited to the items mentioned in the article.

From where data/document is obtainable
f_taghlili@yahoo.com

What processes are involved for a request to access data/document
After communicating through the e-mail address and the topic related to the research, and the reason for the request, the results will be presented.

Comments