

# 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 conducted on 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 enoxaparin (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

Measurement 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

Measurement 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

##### City

Babol

##### Province

Mazandaran

##### Postal code

4715763561

##### Phone

+98 11 3239 9079

##### Email

fa\_taghlili@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Islamic Azad University

##### Full name of responsible person

Iman dadashi

##### Street address

گرچی آباد، دانشگاه آزاد اسلامی واحد بابل

##### City

Babol

##### Province

Mazandaran

##### Postal code

4715763561

##### Phone

+98 11 3241 5061

##### Email

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 تغلیلی

##### Position

Faculty member

##### Latest degree

Master

##### Other areas of specialty/work

Nursery

##### Street address

Gorgiabad., Islamic Azad University of Babol

##### City

Babol

##### Province

Mazandaran

##### Postal code

4715763561

##### Phone

+98 11 3241 5163

##### Email

Fa\_taghlili@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Fatemeh taghlili

**Position**

Faculty memeber

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

**Street address**

Gorgiabad., Islamic Azad University of Babol

**City**

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**Province**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Fatemeh taghlili

**Position**

Faculty member

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

**Street address**

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**City**

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**Province**

Mazandaran

**Postal code**

4715763561

**Phone**

+98 11 3241 5163

**Email**

Fa\_taghlili@yahoo.com

## 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**