

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Effects of Arnica ointment and cold compress on pain and bruising caused by enoxaparin injection

Protocol summary

Summary

This single blind clinical trial will be done with the aim to comparison of the effects of Arnica ointment and Cold Compress on Pain and bruising caused by enoxaparin injection. A total of 90 patients admitted in the 22-Bahman Hospital in Gonabad will be enrolled. Patients will be selected in available method and randomly divided into three groups (Arnica, cold compress and control) will be allocated. in Arnica group, 1 gram of Arnica Ointment will apply to the injection site and then 30-second duration injection will be performed. In Cold Compress group, 4×2×2 size of ice will apply to the injection site for 5 minutes before the injection and then 30-second duration injection will be performed and there is not any intervention in the control group. Pain intensity is measured through VAS after injection. After that a circle with the radius of 5 cm is drawn around it by a waterproof marker. in the Arnica and cold compress groups, intervention for the patient will be conducted three times a day for three days. Injection-site bruising will measured at 24, 48 and 72 hours after injection by cooperators who don't know the patient's group through a millimeter ruler. If there is not any bruising, it is recorded and if there is, the biggest diameter of it measured and recorded. The bruising with size less 5 millimeter, will not be called as bruising and The bruising with size more 5 millimeter will be called bruising. Then sizes of bruising will be compared during 3 days for all participant.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017020832465N1**

Registration date: **2017-03-17, 1395/12/27**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-03-17, 1395/12/27

Registrant information

Name

Eshrat Jameiati

Name of organization / entity

Gonabad University of Medical Sciences

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Phone

+98 51 5722 1606

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Recruitment status

Recruitment complete

Funding source

Gonabad University of Medical Sciences

Expected recruitment start date

2016-11-21, 1395/09/01

Expected recruitment end date

2017-03-15, 1395/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Arnica ointment and cold compress on pain and bruising caused by enoxaparin injection

Public title

Effects of Arnica ointment and cold on pain and bruising caused by enoxaparin injection

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Physician's order to receive subcutaneous enoxaparin, Agreed to participate in the study and complete and sign the consent form, orientation to person/place/time/situation, no prescription of narcotic analgesics 4 hours before injection, Exclusion criteria: patient Not wanting to continue studying, allergy to Arnica ointment, loss of consciousness or died patient during the study, coagulation disorders, Presence of scar tissue, any skin lesion or unilateral senso neural obvious defects, receiving other anticoagulants such as warfarin and heparin

Age

From **30 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

University of Medical Sciences

Street address

Gonabad University of Medical Sciences, Next to the Asian Road, Khorasan Razavi Province, Iran, Islamic Republic Of

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9691793718

Approval date

2016-11-09, 1395/08/19

Ethics committee reference number

IR.GMU.REC.1395.71

Health conditions studied**1****Description of health condition studied**

Injection pain

ICD-10 code

R52.0

ICD-10 code description

Acute pain

2**Description of health condition studied**

Bruising associated with injection

ICD-10 code

T14.0

ICD-10 code description

Superficial injury of unspecified body region

Primary outcomes**1****Description**

Measuring pain severity

Timepoint

Immediately after injection

Method of measurement

using visual analog scale

Secondary outcomes**1****Description**

Measuring of bruise

Timepoint

24 - 48 and 72 hours after injection

Method of measurement

using ruler

Intervention groups**1****Description**

In this method 1 gr Arnica ointment is placed on the injection site with holder dressing 60 minute before the injection and dressing is removed after the one hour, then area is cleaned and injection is performed. Then Arnica ointment at the injection site is used 3 times a day for 3 days

Category

Prevention

2**Description**

In this method, a piece of ice the size of 4*2*2 Cm is placed inside the latex gloves and two layers of gas is placed on the injection site 5 minute before the injection, Then piece of ice is used at the injection site for 5 minutes 3 times a day for 3 days.

Category

Prevention

3**Description**

Injection Enoxaparin without interference

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

22 Bahman Hospital

Full name of responsible person

Eshrat jameiati

Street address

Gonabad- Naser Khosrow Street

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Gonabad

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Gonabad University of Medical Sciences

Full name of responsible person

The Vice-chancellery for Research and Technology

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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

Gonabad 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**

Gonabad University of Medical Sciences

Full name of responsible person

Eshrat Jameiati

Position

Nursing graduate student

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cardiologist

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Position

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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