

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Comparison of Emla cream and Cold compress on the injection site pain intensity in Enoxaparin

Protocol summary

Summary

This study aims to compare the effect of EMLA cream and local cold application on the occurrence of pain at the injection site in subcutaneous Enoxaparin injections. The occurrence of pain is one of the most prevalent causes of suffering patients and the most common reason of admission patients to the health centers . This is commonly caused by mechanical, chemical, thermal stimuli . these stimuli lead to some problems such as bruise and pain at the injection site in subcutaneous Enoxaparin injection hospitalized patients in this study are 53 patients who receive Enoxaparin randomly and they were divided in to three groups. in the first group, 1.5 gram of EMLA cream will apply to the injection site and then injection will be performed. In the second group, 4x2x2 size of ice will apply to the injection site for 5 minutes before the injection and then injection will be performed and there is not any injection in third group .following each injection, the patient's pain intensity by using VAS method will be measured after injection, by 5 and 10 minutes after the injection and then the severe pain intensity will be established as the criteria for pain

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013100914956N1**

Registration date: **2014-01-22, 1392/11/02**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-01-22, 1392/11/02

Registrant information

Name

Somayeh Zeighamian

Name of organization / entity

Medical University of Shahid Sadoughi Yazd, school of Nursing & M

Country

Iran (Islamic Republic of)

Phone

+98 35 1824 1751

Email address

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Recruitment status

Recruitment complete

Funding source

Shahid Sadoughi University of Medical Sciences

Expected recruitment start date

2013-12-27, 1392/10/06

Expected recruitment end date

2014-04-08, 1393/01/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Emla cream and Cold compress on the injection site pain intensity in Enoxaparin

Public title

Comparison of Emla cream and Cold on the injection site pain in Enoxaparin

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: age between 18-65 years old; full consciousness; ability to communicate; not a severe pain in other areas; no history of prescribed Enoxaparin; no scarring and lesions at the injection site and no history of

allergy to lidocaine & Prilocain. Exclusion criteria: loss of consciousness; sensorimotor disorders; injection of other drug in the abdomen during the study, and two days before the study; prescription of narcotic and non-narcotic analgesics 2 hours before injection; allergy to EMLA cream; the development of diabetic neuropathy.

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: **53**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Medical University of Shahid Sadoughi, Yazd

Street address

School of Nursing and Midwifery, Bu Ali St, Safaeyeh Avenue Yazd

City

Yazd

Postal code

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

105274

Health conditions studied

1

Description of health condition studied

Injection pain

ICD-10 code

R52.0

ICD-10 code description

Acute pain

Primary outcomes

1

Description

Injection pain

Timepoint

Immediate, 5 & 10 minute after injection

Method of measurement

Using the VAS scale & record severe pain intensity

Secondary outcomes

empty

Intervention groups

1

Description

First method: Injection Enoxaparin without interference (Subcutaneous injection of Enoxaparin-Na for 10 seconds in the right or left side of abdomen)

Category

Prevention

2

Description

Second method: In this method 1/5 gr Emla cream 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

Category

Prevention

3

Description

Third method: In this method, a piece of ice the size of 4*2*2 Cm is placed inside the latex gloves and is placed on the injection site 5 minute before the injection

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sadoughi hospital, Yazd

Full name of responsible person

Somayeh Zeighamian

Street address

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Sadoughi University of Medical Sciences Yazd,
School of Nursing & Midwifery

Full name of responsible person

Farnia Farahnaz, PhD

Street address

School of Nursing & Midwifery, Bu Ali St, Safaeyeh
Avenue

City

Yazd

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Sadoughi University of Medical Sciences Yazd,
School of Nursing & Midwifery

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

Shahid Sadoughi University of Medical Sciences Yazd,
School of Nursing & M

Full name of responsible person

Somayeh Zeighamian

Position

Nursing graduate student

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)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty