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 into 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, 4×2×2 size of ice will apply to the injection site for 5 minutes before the injection and then injection will be performed. In the second group, 4×2×2 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
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Recruitment status
Recruitment complete
Funding source Shahid Sadoughi University of Medical Sciences

Expected recruitment start date
2013-12-27, 1393/10/06
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 blind

Blinding description

Placebo
Not used

Assignment
Crossover

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
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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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