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 third group, there is no injection. 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

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, 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**

**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: 89715

**Approval date**
- 2010-08-20, 1389/05/29

**Ethics committee reference number**
- 105274

**Health conditions studied**

**Description of health condition studied**
- Injection pain

**ICD-10 code**
- R52.0

**ICD-10 code description**
- Acute pain

**Primary outcomes**

1. **Description**
- Injection pain

2. **Timepoint**
- Immediate, 5 & 10 minute after injection

3. **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)

2. **Category**
- Prevention

3. **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

4. **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

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