Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effect Emla Cream، local lavender essential oil and Cold Compress on the pain intensity of the injection site and Comfort of heart Patients Receiving Enoxaparin

Protocol summary

Study aim
Comparison of the effect Emla Cream، local lavender essential oil and Cold Compress on the pain intensity of the injection site and Comfort of ischemic heart disease Receiving Enoxaparin

Design
randomize clinical trial Participants were randomly random allocation method is used by random computer numbers

Settings and conduct
After approval of the research project by the Research Council of the University of Medical Sciences and obtaining permission from the Ethics committee of the University of Medical Sciences, and coordination with the officials of the Shahid Beheshti Hospital, the researcher referred to Shahid Beheshti Medical Center the week and with the help of the Center staff, after expressing the research goals and ensuring patients are kept confidential and obtain informed written consent from them random allocation patients who have been admitted to the study

Participants/Inclusion and exclusion criteria
patient with ischemic heart disease receive enexaprin with physician order

Intervention groups
Method 1: 1 gram of EMLA cream. of this cream is fixed 60 minutes before injection at the injection site using the dressing retainer and after 60 minutes, the skin will be cleaned and injected method 2: 3×2×2 size of ice will apply to the injection site for 5 minutes before the injection metd 3: 2 ml of lavender oil 10% will apply for 5 minutes before injection on the injection site and after 20 minutes, the skin will be cleaned and injected. Method 4: Enoxaparin injection without intervention (subcutaneous injection of enoxaparin sodium in 10 seconds on the right or left abdomen) And these methods are separate individually for each group

Main outcome variables
The amunt of pain in the injection site and the patient's comfort

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20100829004655N9**
Registration date: **2018-03-25, 1397/01/05**
Registration timing: **prospective**

Last update: **2018-03-25, 1397/01/05**
Update count: **0**

Registration date
2018-03-25, 1397/01/05

Registrant information

Name
Mohsen Taghadosi

Name of organization / entity
Kashan University of Medical Sciences

Country
Iran (Islamic Republic of)

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taghadosi_m@kaums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-04-04, 1397/01/15

Expected recruitment end date
2018-09-21, 1397/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect Emla Cream، local lavender essential oil and Cold Compress on the pain intensity of the injection site and Comfort of heart Patients Receiving Enoxaparin

Public title

Comparison of the effect Emla Cream، local lavender essential oil and Cold Compress on the pain intensity of the injection site and Comfort of heart Patients Receiving Enoxaparin

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

1.age between 18-85 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 no history of allergy to lidocaine & Prilocain no history of allergy to Lavender

Exclusion criteria:

loss of consciousness prescription of narcotic and non-narcotic analgesics 2 hours before injection injection of other drug in the abdomen during the study

Age

From **18 years** old to **85 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

The sampling method is continuous The patients were randomly assigned to three intervention groups and one control group

Blinding (investigator's opinion)

Double blinded

Blinding description

patient and researcher measurement pain and comfort are blind

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kashan University of Medical Sciences

Street address

Ghotb Ravandi Blvd, Kashan

City

kashan

Province

Isfehan

Postal code

8715981151

Approval date

2018-01-01, 1396/10/11

Ethics committee reference number

IR.KAUMS.NUHEPM.REC.1396.31

Health conditions studied

1

Description of health condition studied

Injection pain

ICD-10 code

G89.18

ICD-10 code description

Other acute postprocedural 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

2

Description

the amount Patient comfort

Timepoint

Immediate,5 &10 minute after injection

Method of measurement

visual scale of comfor& record severe comfort intensity Using the

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group :In this method 1gr 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

2

Description

Second intervention group: In this method, a piece of ice the size of 3*2*2 Cm is placed inside the latex gloves and is placed on the injection site 5 minute before the injection

Category

Prevention

3

Description

Third intervention group:2 ml of lavender oil 10% will apply for 5 minutes before injection on the injection site and after 20 minutes, the skin will be cleaned and injected

Category

Prevention

4

Description

Control group:Enoxaparin injection without intervention

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashan University of Medical Sciences

Full name of responsible person

Mohsen Taghadosi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

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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

Kashan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

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

Kashan University of Medical Sciences

Full name of responsible person

badry torki

Position

Medical Surgical Nursing

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
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Position
faculty member

Latest degree
Ph.D.

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Nursery

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
The total potential data can be shared after unidentifiable people

When the data will become available and for how long
Start the access period 6 months after printing the results

To whom data/document is available
Only available to scholars working in academia and academia

Under which criteria data/document could be used
If you observe the trust and mention the source, data is available for researchers

From where data/document is obtainable
Send the following e-mail to the following address: taghadosi_m@kaums.ac.ir

What processes are involved for a request to access data/document
After receiving the letter via email, your request will be reviewed within 2 weeks and the data will be sent to the applicant at the discretion

Comments