

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effect of ice pack and lidocaine ointment in the pain of subcutaneous enoxaparin injection

Protocol summary

Study aim

The aim of this study is to compare the effect of topical lidocaine ointment and ice pack on the pain of enoxaparin injection

Design

In this study, 108 cardiac patients are placed in intervention group 1, 2, or 3 according to the inclusion criteria and selected random sampling by block random allocation

Settings and conduct

This study is a randomized, block-based clinical trial with 108 cardiac patients receiving enoxaparin and admitted to the cardiac intensive care unit of Amir Kabir Hospital in Arak. Patients with inclusion criteria are included. For intervention group 1, cryotherapy is used, for intervention group 2, lidocaine ointment is used and for the control group, no intervention is performed. Enoxaparin injection is performed in the same way in all patients by one person

Participants/Inclusion and exclusion criteria

Major entry requirements include: age between 30 and 65 years; ability to communicate and answer questions and show pain with visual analogue scale tools; stable clinical status; no drug addiction; no history of allergies to local anesthetics drugs Exclusion criteria include; cancellation of further study; discharge; transfer; death of the patient

Intervention groups

Group 1 is intervened with an ice pack for one minute. Immediately after removing the ice pack, the injection site is disinfected as usual and subcutaneous injection is performed Group 2 is treated with 5% lidocaine ointment in the amount of 2 g for 30 minutes. Then it is removed and subcutaneous injection is performed there is no intervention in the control group

Main outcome variables

Reduction of pain caused by enoxaparin injection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200820048466N1**

Registration date: **2020-09-13, 1399/06/23**

Registration timing: **prospective**

Last update: **2020-09-13, 1399/06/23**

Update count: **0**

Registration date

2020-09-13, 1399/06/23

Registrant information

Name

Freydoun Shahivand

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 66 4342 2302

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-20, 1399/06/30

Expected recruitment end date

2020-12-20, 1399/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of ice pack and lidocaine ointment in the pain of subcutaneous enoxaparin injection

Public title
Comparison of the effect of ice pack and lidocaine ointment in the pain of subcutaneous enoxaparin injection

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Age 30-65 years Awareness Ability to communicate and answer questions and show the amount of pain Stability of the clinical condition No drug addiction No history of allergies to local anesthetics No known mental illness
Exclusion criteria:
Canceling Discharge Transfer Patient death

Age
From **30 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Care provider
- Outcome assessor

Sample size
Target sample size: **108**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, 108 heart patients were selected according to the inclusion criteria and by available sampling and block random allocation, by assigning the letter A to the ice pack group, the letter B to the lidocaine group and the letter C to the control group in six cases. ABC, ACB, BAC, BCA, CAB, CBA are written on separate sheets and thrown into a container and one of the sheets is randomly taken out of the container and the composition written on it is written down and again. That sheet is thrown into the container. Because the sample size in this study is 108 patients, this operation should be repeated 36 times. Each time the composition written on each sheet is written in the sequence written on the previous sheet. Then, for each letter, a number from one to one hundred and eight is assigned to the letters written in sequence, and each letter is placed in an envelope and the letter number is written on the envelope. Each time a patient is selected, one of the envelopes is opened in the order written on the envelope and it is determined that the patient should be in intervention group 1, 2 or 3, they are divided into three groups

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, to avoid bias, the use of ice packs and lidocaine ointment and enoxaparin injection is performed by one person in the group and is measured by another person in the group

Placebo
Not used

Assignment
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak university of medicine

Street address

Sardasht Square

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2020-06-28, 1399/04/08

Ethics committee reference number

IR.ARAKMU.REC.1399.134

Health conditions studied

1

Description of health condition studied

Pain due to Enoxaparin injection

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Patient pain rate with VAS instrument

Timepoint

Immediately after injection

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

Pain Rate

Timepoint

Immediately

Method of measurement

VAS

Intervention groups

1

Description

Intervention group : group 1 patients undergo ice bag intervention. one minute before the injection, the ice pack is placed on the site where the enoxaparin is to be performed. immediately after removing the ice pack, the injection site is disinfected in the usual way using normal saline and subcutaneous injection is performed by one person in both groups, immediately after the injection of the patients pain with VAS instrument measured and recorded.

Category

Treatment - Devices

2

Description

Intervention group: Group 2 patients underwent the intervention with 5% lidocaine ointment. 2 g equals 15 cm (from 5% lidocaine ointment tube weighing 15 g) was measured with a Scaltec laboratory scale with an accuracy of 0.01 g. After performing several measurements under the same conditions, the length of the ointment used was calculated to be 15 cm. Apply lidocaine on the calibrated pad and place it on the stand. After 30 minutes, the ointment is removed from the stand. Using a checklist, the possible side effects of lidocaine ointment are investigated and recorded. Side effects of topical lidocaine include redness and irritation of the lidocaine ointment . Using a normal saline impregnated pad, the injection site is cleansed and the subcutaneous injection is performed by one person in each of the three groups. Immediately after the injection, the patient's pain is measured and recorded with a VAS instrument.

Category

Treatment - Drugs

3

Description

Control group: The control group did not perform any intervention and immediately after injection, the patient's pain was measured and recorded with a VAS instrument

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir Kabir Hospital

Full name of responsible person

Esmail Moshiri

Street address

Shahid Shiroudi Ave.

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3819693345

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

President for research and technology

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3848176593

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research@arakmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Fereydoun Shahivand

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Article

When the data will become available and for how long

2020

To whom data/document is available

researchers

Under which criteria data/document could be used

researchers

From where data/document is obtainable

fshahivand93@yahoo.com

What processes are involved for a request to access data/document

email fshahivand93@yahoo.com

Comments