

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

Comparing the effectiveness of the duration and site of subcutaneous injection of enoxaparin on pain intensity and bruising size in patients hospitalized to the Department of Cardiac Care

Protocol summary

Study aim

Comparing the effectiveness of the duration and site of subcutaneous injection of Enoxaparin on pain intensity and bruising size in patients hospitalized to the Department of Cardiac Care

Design

Clinical trial with two intervention and parallel groups, single blind and randomized with a sample size of 60 people

Settings and conduct

This single blind clinical trial will be conducted on patients admitted to the Cardiac Care departments of Zahedan Hospitals in 2019. After applying the inclusion criteria and purposive Sampling, Patients will be divided into two intervention groups by simple random sampling. The first group received subcutaneous injection of Enoxaparin in the abdomen and arm area with 30 second method and the second group received subcutaneous injection of Enoxaparin with 5 + 15 seconds method. The intensity of pain will be measured immediately after each injection with the visual-analogue scale of pain. The size of the bruise will be measured 24 and 48 hours after each injection. Determining the intensity of pain and size of bruising will be done by the uninformed researcher of the groups and the injection technique.

Participants/Inclusion and exclusion criteria

All patients admitted to the cardiac care unit with:
Inclusion criteria: Age range 20 to 75 years Being able to understand and express pain
Non-inclusion criteria:
Analgesic use, four hours before the intervention
Swelling, ulcer, scratches and erythema in the injection site

Intervention groups

First group: Subcutaneous injection of Enoxaparin in the abdomen and arm area with a 30 second method.
Second group: Subcutaneous injection of Enoxaparin in

the abdomen and arm area with a 15 + 5 second method.

Main outcome variables

The intensity of pain caused by subcutaneous injection of Enoxaparin in the abdomen and arm area, The size of the bruising caused by subcutaneous injection of Enoxaparin in the abdomen and arm area

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150106020581N2**

Registration date: **2019-03-13, 1397/12/22**

Registration timing: **registered_while_recruiting**

Last update: **2019-03-13, 1397/12/22**

Update count: **0**

Registration date

2019-03-13, 1397/12/22

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5722 3028

Email address

abbasi.ali@gmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-20, 1397/12/01

Expected recruitment end date

2019-04-21, 1398/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing the effectiveness of the duration and site of subcutaneous injection of enoxaparin on pain intensity and bruising size in patients hospitalized to the Department of Cardiac Care

Public title
Effect of time and place of subcutaneous injection of Enoxaparin on the severity of pain and size of bruising

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Age range 20 to 75 years Physiological stable condition
Being able to understand and express pain Platelet count in normal range Body mass index (BMI) ranging from 18.5 to 30
Exclusion criteria:
Analgesic use, four hours before the intervention
Swelling, ulcer, scratches and erythema in the injection site Muscular and dermal disease and Known coagulopathy

Age
From **20 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Investigator

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Subjects will be randomly assigned to one of two study groups using table of random numbers and will receive the intervention of the same group.

Blinding (investigator's opinion)
Single blinded

Blinding description
The size of the bruise and the severity of pain will be measured by another person.(Blind researcher)

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Zahedan university of medical sciences

Street address

Administrative complex of University of Medical Sciences, Khalij Fars blvd, Dr Hesabi square, Zahedan city

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

98167-43463

Approval date

2019-02-03, 1397/11/14

Ethics committee reference number

IR.ZAUMS.REC.1397.415

Health conditions studied

1

Description of health condition studied

Pain and bruise

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain intensity

Timepoint

Immediately after subcutaneous injection of Enoxaparin

Method of measurement

Visual-Analogue Scale of pain(VAS)

2

Description

Bruising size

Timepoint

24 and 48 hours after each subcutaneous injection of Enoxaparin

Method of measurement

Transparent millimeter ruler

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Enoxaparin medicine according to physician's orders (40 or 60 mg) will be injected subcutaneously into the abdomen and arm area with 30 seconds method. In this method, After the needle is inserted into the subcutaneous space, Enoxaparin will be injected for 30 seconds.

Category

Treatment - Other

2

Description

Intervention group: Enoxaparin medicine according to physician's orders (40 or 60 mg) will be injected subcutaneously into the abdomen and arm area with 5+15 seconds method. In this method, After the needle is inserted into the subcutaneous space, Enoxaparin will be injected for 15 seconds. After the injection is completed, the needle for 5 seconds remaining in the subcutaneous space and will be removed later.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali ebn abitaleb hospital

Full name of responsible person

Ali Abbasi Mendi

Street address

Ali ebn abitaleb hospital, Slammat Blvd, Persian Gulf Highway, Zahedan city

City

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abbasi.ali@gmu.ac.ir

Web page address

<http://en.alihos.zaums.ac.ir/#English>

2

Recruitment center

Name of recruitment center

Khatam(s) hospital

Full name of responsible person

Ali Abbasi Mendi

Street address

Jamejam Blvd, Khatam(s) hospital, Zahedan city

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Email

abbasi.ali@gmu.ac.ir

Web page address

<http://khatam.zaums.ac.ir/#FA>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Dr noormuhammad bakhshani

Street address

Zahedan University of Medical Sciences, Khaliye Fars Blvd, Dr Hesabi Square, Zahedan city

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Phone

+98 54 3329 5796

Email

bakhshani@zaums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Ali Abbasi Mendi

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Behdasht blvd, Faculty of Nursing and Midwifery,
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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Zahedan University of Medical Sciences

Full name of responsible person

Ali Abbasi Mendi

Position

Nurse

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Person responsible for updating data**Contact****Name of organization / entity**

Zahedan University of Medical Sciences

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

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

Study Protocol

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

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

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

Analytic Code

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

Data Dictionary

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