

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 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, Slamati Blvd, Persian Gulf Highway, Zahedan city

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**

9816743111

**Phone**

+98 54 3329 5570

**Email**

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

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**

9815733169

**Phone**

+98 54 3322 0501

**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, Khalije Fars Blvd, Dr Hesabi Square, Zahedan city

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**

98167-43463

**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,  
Zahedan city

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**

9816913396

**Phone**

+98 54 3344 2482

**Email**

abbasi.ali@gmu.ac.ir

**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

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Behdasht blvd, Faculty of Nursing and Midwifery,  
Zahedan city

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**

9816913396

**Phone**

+98 54 3344 2482

**Email**

abbasi.ali@gmu.ac.ir

**Person responsible for updating data****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,  
Zahedan city

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**

9816913396

**Phone**

+98 54 3344 2482

**Email**

abbasi.ali@gmu.ac.ir

**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