

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Effect of Enoxaparin on serum level of activated anti-factor XA in myocardial infarction patients with acute coronary syndrome: a before-after clinical trial

Protocol summary

Study aim

To assess the effect of Enoxaparin on serum level of activated anti-factor XA in myocardial infarction patients with acute coronary syndrome.

Design

A before-after clinical trial.

Settings and conduct

The eligible myocardial infarction patients with acute coronary syndrome who will refer to Farshchian Heart Hospital during the study period will be enrolled into the trial.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 90 years; myocardial infarction with acute coronary syndrome. Exclusion criteria: Low blood platelet; heparin induced thrombocytopenia; uncontrolled hypertension; bacterial endocarditis; hemorrhagic stroke; gastric or duodenal ulcer; severe renal insufficiency; diabetic retinopathy; coagulation disorders.

Intervention groups

Intervention group: Enoxaparin 1 mg/kg subcutaneously every 12 hours in people over 75 years of age or with renal creatinine clearance less than 30 ml/min. In people under 75 years of age or with renal creatinine clearance greater than 30 ml/min, in addition to the above dose, 30 mg of Enoxaparin is injected as a single intravenous dose. Control group: In comparison with before intervention

Main outcome variables

Primary outcome: Assessing serum level of activated anti-factor XA before intervention and 12 hours after intervention through laboratory test.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N198**

Registration date: **2017-12-03, 1396/09/12**

Registration timing: **registered_while_recruiting**

Last update: **2017-12-03, 1396/09/12**

Update count: **0**

Registration date

2017-12-03, 1396/09/12

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-09-27, 1395/07/06

Expected recruitment end date

2018-02-27, 1396/12/08

Actual recruitment start date

2016-09-27, 1395/07/06

Actual recruitment end date

2018-02-27, 1396/12/08

Trial completion date

empty

Scientific title

Effect of Enoxaparin on serum level of activated anti-factor XA in myocardial infarction patients with acute coronary syndrome: a before-after clinical trial

Public title

Effect of Enoxaparin on serum level of activated anti-factor XA in myocardial infarction patients with acute coronary syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 18 to 90 years myocardial infarction with acute coronary syndrome

Exclusion criteria:

Low blood platelet Heparin induced thrombocytopenia Uncontrolled hypertension Bacterial endocarditis Hemorrhagic stroke Gastric or duodenal ulcer Severe renal insufficiency Diabetic retinopathy Coagulation disorders

Age

From **18 years** old to **90 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **100**

Actual sample size reached: **100**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

This is a before after trial without randomization. Blinding is not possible.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2016-06-25, 1395/04/05

Ethics committee reference number

IR.UMSHA.REC.1395.177

Health conditions studied

1

Description of health condition studied

Myocardial infarction with acute coronary syndrome

ICD-10 code

I21

ICD-10 code description

ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction

Primary outcomes

1

Description

Assessing serum level of activated anti-factor XA

Timepoint

Before intervention and 12 hours after intervention

Method of measurement

Through laboratory test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Enoxaparin 1 mg/kg subcutaneously every 12 hours in people over 75 years of age or with renal creatinine clearance less than 30 ml/min. In people under 75 years of age or with renal creatinine clearance greater than 30 ml/min, in addition to the above dose, 30 mg of Enoxaparin is injected as a single intravenous dose.

Category

Treatment - Drugs

2

Description

Control group: In comparison with before intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Farshchian Heart Hospital

Full name of responsible person

Dr Jila Hashemi

Street address

Farshchian Heart Hospital, Shahid Fahmideh Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 1740

Email

cardio.jila@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

38380717

Phone

+98 81 3838 0717

Email

info.research@umsha.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Dr Jila Hashemi

Position

Resident of Cardiology

Latest degree

Medical doctor

Other areas of specialty/work

Cardiology

Street address

Farshchian Heart Hospital, Shahid Fahmideh Ave.

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Phone

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Email

cardio.jila@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Shahram Homayoonfar

Position

Cardiologist

Latest degree

Specialist

Other areas of specialty/work

Cardiology

Street address

Farshchian Heart Hospital, Shahid Fahmideh Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 1740

Email

shahram1338@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Master

Other areas of specialty/work

Epidemiology

Street address

School of Public Health, Hamadan University of
Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0090

Email

poorolajal@umsha.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