Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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)

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+98 81 1838 0090

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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

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+98 81 3838 1740

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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
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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
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

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
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Position
Cardiologist

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Specialist

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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
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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