Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of efficacy and safety of Heparin and Enoxaparin versus control group in patients undergoing primary percutaneous intervention: An open labelled randomized clinical trial

Protocol summary

Study aim

Determining and comparing the efficacy and safety of heparin and enoxaparin with the control group in patients undergoing primary angioplasty

Design

A controlled, parallel-group, open-label, randomized clinical trial on 171 patients. The website http://www.randomization.com/ will be used for randomization.

Settings and conduct

In this open label, clinical trial study, patients aged 18 to 65 years with acute myocardial infarction with ST segment elevation, who will undergo primary PCI in the emergency room of Dr. Heshmat Rasht Hospital in the period of 2023-2024, in the service of an international cardiologist will enter the study. According to inclusion and exclusion criteria,all these patients will be included in the study after completing the informed consent form. The current clinical trial has one control and two intervention groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria:myocardial infarction with ST segment elevation. Non-inclusion criteria: having coagulopathy, underlying bleeding disorders, history of mechanical valve, presence of other indications for receiving anticoagulants, absolute prohibition of receiving anticoagulants, GFR lower than 30 and liver failure

Intervention groups

The control group includes patients with myocardial infarction who will not receive any injectable anticoagulant from three hours after the sheet removal until the end of the hospitalization period. In the first intervention group, 60 U/kg bolus of unfractionated heparin and then 12 U/kg/h as an infusion will be prescribed from three hours after sheet removal until the end of hospitalization. In the second intervention group, they will be treated with enoxaparin (LMWH) 1 mg/kg twice a day (once every 12 hours) from three hours after sheet removal until the end of the hospitalization period.

Main outcome variables

Stroke, cardiac death and recurrent myocardial infarction in the first 40 days after discharge from the hospital

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220809055645N4**
Registration date: **2023-05-23, 1402/03/02**
Registration timing: **registered_while_recruiting**

Last update: **2023-05-23, 1402/03/02**
Update count: **0**

Registration date

2023-05-23, 1402/03/02

Registrant information

Name

Fatemeh Baharvand

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3361 8177

Email address

dr.baharcardio@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-22, 1402/03/01

Expected recruitment end date

2023-11-22, 1402/09/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of efficacy and safety of Heparin and Enoxaparin versus control group in patients undergoing primary percutaneous intervention: An open labelled randomized clinical trial

Public title
Effect of heparin and enoxaparin in patients undergoing primary angioplasty
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Myocardial infarction with ST segment elevation
Exclusion criteria:
Having coagulopathy Having no consent to participate in the study and follow-up courses Having underlying bleeding disorders, mechanical valve history Presence of other indications for receiving anticoagulants Absolute prohibition of receiving anticoagulants (such as active bleeding at the time of visit, drug sensitivity) GFR lower than 30 liver failure
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **171**
Randomization (investigator's opinion)
Randomized
Randomization description
The method of sampling and randomization will be the blocked randomization method. In this way, each person will be randomly assigned to the intervention or control groups using blocks of size 6 in a ratio of 1:1:1. The website http://www.randomization.com/ will be used for randomization. The list of codes obtained from this website will be provided to project researchers, and every patient with acute myocardial infarction who met the inclusion criteria will be entered into the project based on the assigned code A, B, and C, respectively. In this research, simple random allocation concealment method will be used. In this way, each patient will be assigned a code. In this method, each of the generated random codes will be written on a card. Then they will be placed inside sealed opaque envelopes in random order. In order to maintain the random sequence, the outer surface of the envelopes will be numbered in the same order. Finally, the lid of the letter envelopes will be glued and will be placed in a box respectively. At the time of sampling, based on the order of entry of qualified participants into the study, one of the envelopes will be revealed in the order of opening and the assigned group of that participant.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Guilan University of Medical Sciences
Street address
Cardiovascular Diseases Research Center, Dr. Heshmat Heart Hospital, 15 Khordad Street, Mosalla Square
City
Rasht
Province
Guilan
Postal code
4193955588
Approval date
2023-05-03, 1402/02/13
Ethics committee reference number
IR.GUMS.REC.1402.055

Health conditions studied

1

Description of health condition studied
Acute myocardial infarction
ICD-10 code
I21
ICD-10 code description
ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction

Primary outcomes

1

Description
Incidence of stroke
Timepoint
40 days after primary angioplasty
Method of measurement
By using clinical documents of patients and asking them

2

Description
Cardiac death
Timepoint
40 days after primary angioplasty
Method of measurement
By using clinical documents of patients

3

Description
Recurrent myocardial infarction
Timepoint
40 days after primary angioplasty
Method of measurement
By using clinical documents of patients

Secondary outcomes

1

Description
Mean ejection fraction of the left ventricle
Timepoint
40 days after primary angioplasty
Method of measurement
Echocardiography

Intervention groups

1

Description
Intervention group: The first intervention group includes 57 patients with myocardial infarction who will undergo percutaneous coronary intervention (PCI). These patients will enter the study with their personal consent and after completing the informed consent form. For the participants in the first intervention group, from three hours after removing the sheet until the end of hospitalization, unfractionated heparin 60 U/kg bolus and then 12 U/kg/h will be administered as an infusion.
Category
Treatment - Drugs

2

Description
Intervention group: In the second intervention group, 57 participants will be treated with enoxaparin (LMWH) 1 mg/kg twice a day (once every 12 hours) from three hours after removing the sheet until the end of hospitalization. It should be noted that all these interventions will end after the patient is discharged from the hospital.
Category
Treatment - Drugs

3

Description
Control group: It includes 57 patients with myocardial infarction who will undergo percutaneous coronary intervention (PCI). These patients will enter the study with their personal consent and after completing the informed consent form. Participants in the control group will not receive any injectable anticoagulant from three hours after removing the sheet until the end of their hospitalization.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr. Heshmat heart hospital
Full name of responsible person
Fatemeh Baharvand
Street address
Cardiovascular Diseases Research Center, Dr. Heshmat Heart Hospital, 15 Khordad Street, Mosalla Square
City
Rasht
Province
Guilan
Postal code
4193955588
Phone
+98 13 3361 8177
Fax
+98 13 3366 8718
Email
dr.baharcardio@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Mohammadreza Naghipour
Street address
Cardiovascular Diseases Research Center, Dr. Heshmat Heart Hospital, 15 Khordad Street, Mosalla Square
City
Rasht
Province
Guilan
Postal code
4193955588
Phone
+98 13 3361 8177
Fax
+98 13 3366 8718
Email
dr.baharcardio@gmail.com
Grant name

Grant code / Reference number

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

Title of funding source
Rasht 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
Rasht University of Medical Sciences

Full name of responsible person
Fatemeh Baharvand

Position
Associate professor

Latest degree
Subspecialist

Other areas of specialty/work
Cardiology

Street address
Cardiovascular Diseases Research Center, Dr. Heshmat Heart Hospital, 15 Khordad Street, Mosalla Square

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Guilan

Postal code
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Phone
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Fax
+98 13 3366 8718

Email
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Person responsible for scientific inquiries

Contact

Name of organization / entity
Rasht University of Medical Sciences

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Fatemeh Baharvand

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Fax
+98 13 3366 8718

Email
dr.baharcardio@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Rasht University of Medical Sciences

Full name of responsible person
Fatemeh Baharvand

Position
Associate professor

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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