

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Safety and usefulness of Enoxaparin versus unfractionated heparin in patients with ST elevation myocardial infarction

Protocol summary

Summary

This study was designed to determine whether Enoxaparin was associated with superior efficacy and safety comparing with unfractionated heparin (UFH) in the myocardial infarction with ST-segment elevation (STEMI) setting. Patients aged 18 to 75 years old, with onset of symptoms of acute myocardial infarction within 12 hrs prior to randomization, and ST-segment elevation of 0.1 mV or more in two or more limb leads or at least 0.2 mV in two or more precordial leads were enrolled in this study. Cases with any contraindication to receive streptokinase, cardiogenic shock, receiving glycoprotein IIb/IIIa antagonists or oral anticoagulants within prior days or therapeutic dose of heparin or low molecular-weight heparin within the previous hours, need for anticoagulant therapy and also any other disease that resulted in increasing the risk were excluded. 150 patients with ST-elevation myocardial infarction who were scheduled to receive streptokinase (1.5 million unit infusion per hour) randomly assigned to receive Enoxaparin (40 mg intravenous bolus then 1 mg/kg subcutaneously BID for at least 5 days) or unfractionated heparin (UFH) [according to Ratke] 24 to 48 hours after streptokinase for at least 5 days. A coronary angiography was done for the patients before discharge. Two groups were compared in terms of thrombolysis in myocardial infarction (TIMI), grade III flow (patency) on angiography, ST-segment resolution at 90 min on ECG; and estimation of ejection fraction using angiography.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138711271695N1**

Registration date: **2009-04-25, 1388/02/05**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2009-04-25, 1388/02/05

Registrant information

Name

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Name of organization / entity

Bushehr University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences and Health Services

Expected recruitment start date

2006-06-22, 1385/04/01

Expected recruitment end date

2008-03-18, 1386/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Safety and usefulness of Enoxaparin versus unfractionated heparin in patients with ST elevation myocardial infarction

Public title

Safety and usefulness of Enoxaparin versus unfractionated heparin in patients with ST elevation

myocardial infarction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Age range 18 to 75 years old, onset of symptoms of acute myocardial infarction within 12 hrs before randomization, ST-segment elevation of 0.1 mV or more in two or more limbs leads or at least 0.2 mV in two or more precordial leads. Exclusion Criteria:

Contraindications to streptokinase, cardiogenic shock, receiving glycoprotein IIb/IIIa antagonists or oral anticoagulants within the prior days or therapeutic dose of heparin or low molecular-weight heparin within the previous hours, need for anticoagulant therapy and also any other disease that resulted in increasing risk

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences and Health Services

Street address

Faculty of Medicine, Poursina St.

City

Tehran

Postal code

Approval date

2006-06-18, 1385/03/28

Ethics committee reference number

237

Health conditions studied

1

Description of health condition studied

Ischaemic heart diseases

ICD-10 code

I21

ICD-10 code description

Acute myocardial infarction

Primary outcomes

1

Description

ST-segment resolution

Timepoint

90 minutes after intervention

Method of measurement

ECG

2

Description

Ejection Fraction

Timepoint

during 5-10th day of admission

Method of measurement

Angiography

3

Description

Thrombolysis in Myocardial Infarction (TIMI) flow grade 3 (patency)

Timepoint

during 5-10th day of admission

Method of measurement

Through angiography

Secondary outcomes

empty

Intervention groups

1

Description

Streptokinase (1.5 million units intravenously over 1 h) plus unfractionated heparin for a minimum of 48 hours and adjusted to the activated partial thromboplastin time according to the American Heart Association/American College of Cardiology guidelines, including the duration of therapy. Treatment was continued for a minimum of 4 days, up to 10th day or when angiography was to be done, whichever was earlier

Category

Treatment - Drugs

2

Description

Streptokinase (1.5 million units intravenously over 1 h)

plus Enoxaparin was administered as an intravenous bolus (40 mg) and then subcutaneously every 12 hrs (1 mg/kg) with a maximum of 100 mg for the first two subcutaneous injections

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shariati Hospital

Full name of responsible person

Mohammad Reza Pourbehi

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

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Grant name

237

Grant code / Reference number

237

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

Yes

Title of funding source

Tehran University of Medical Sciences and Health Services

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Bushehr University of Medical Sciences and Health

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Full name of responsible person

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty