

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Incidence of clinical sign and symptom of acute ischemia and vascular complication with Enoxaparin during stenting in comparison with heparin

Protocol summary

Summary

Unfractionated heparin (UFH) is the standard antithrombotic agent in elective percutaneous coronary intervention (PCI), but it has its own limitations. Several mostly uncontrolled studies have suggested intravenous Enoxaparin as a safe and effective alternative. Our main goal was to evaluate the safety of Enoxaparin over UFH in elective PCI. We randomly assigned 195 patients undergoing PCI to receive 0.75 mg per kilogram of body weight Enoxaparin or 10000 IU unfractionated heparin. All patients also took oral Aspirin 325 mg/day and Clopidogrel 450 mg before the procedure. Patients were recommended remaining on Clopidogrel for at least 3 months. These two interventions was compared regarding prevention of thrombosis and bleeding complications.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138710101525N1**

Registration date: **2009-12-20, 1388/09/29**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2009-12-20, 1388/09/29

Registrant information

Name

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Name of organization / entity

Cardiovascular Research Center, Shiraz University of Medical Science

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2004-10-31, 1383/08/10

Expected recruitment end date

2006-10-31, 1385/08/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Incidence of clinical sign and symptom of acute ischemia and vascular complication with Enoxaparin during stenting in comparison with heparin

Public title

Safety of Enoxaparin versus unfractionated heparin in patients undergoing percutaneous coronary intervention using drug eluting stents: A pilot study

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Patients with atherosclerotic coronary artery disease (chronic stable angina or acute coronary syndromes) were included if they were candidate for PCI as a result of uncontrolled anginal pain, unresponsive to the maximum dose of nitrates or incidence of adverse drug reactions in which it was impossible to continue medical treatment, Patients with clinical sign of heart failure and ischemic involvement of a relatively large segment of myocardium Exclusion criteria: Age 75 years

or older, presence of renal failure defined as creatinine clearance of 30 ml/min and over, creatinine ≥ 2.5 mg/dl in male and creatinine ≥ 2.0 mg/dl in female participants, use of bare-metal stents, presence of primary PCI, receiving heparin or LMWH before randomization, unacceptable prothrombin time (PT) or platelet count, presence of platelet functional disorders or coagulopathies, or hypercoagulopathy syndromes.

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 200

Randomization (investigator's opinion)

Randomized

Randomization description**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**

Shiraz University of Medical Sciences

Street address

Zand ave.

City

Shiraz

Postal code**Approval date**

2008-08-18, 1387/05/28

Ethics committee reference number

CT-87-4188

Health conditions studied**1****Description of health condition studied**

Coronary Artery Disease

ICD-10 code

I25

ICD-10 code description

Chronic ischaemic heart disease

Primary outcomes**1****Description**

The incidence of major bleedings

Timepoint

during the first 24 hours following the index PCI

Method of measurement

Major bleeding was defined as clinically overt bleeding causing a decrease in hemoglobin ≥ 3 g/dl requiring transfusion of packed red cells or whole blood, bleedings which require surgical intervention to stop bleeding at the femoral sheath insertion site, intracranial bleeding, and retroperitoneal bleeding.

2**Description**

The incidence of minor bleedings

Timepoint

During the first 24 hours following the index PCI

Method of measurement

by observation

Secondary outcomes**1****Description**

The incidence of in-stent acute coronary thrombosis

Timepoint

during 24 hours after PCI

Method of measurement

by Observation

Intervention groups**1****Description**

An intravenous bolus of 10000 IU unfractionated heparin, adjusted for activated clotting time according to current guidelines

Category

Prevention

2**Description**

Intravenous Enoxaparin at a dose of 0.75 mg per kilogram during the procedure

Category

Prevention

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

cat-lab of Faghihi Hospital

Full name of responsible person
Street address
City
Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice-chancellor for Research Affairs, Shiraz University of Medical Sciences

Full name of responsible person
Vice-chancellor for Research Affairs, Shiraz University of Medical Sciences

Street address
7th Floor, Central Building of Shiraz University of Medical sciences, Zand ave., Shiraz, Iran

City
Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice-chancellor for Research Affairs, Shiraz University of Medical Sciences

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
Cardiovascular Research Center, Shiraz University of Medical Sciences

Full name of responsible person
Zahra Daneshvar

Position
Research affairs expert

Other areas of specialty/work

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Proffesor of Cardiology in Shiraz University of Medical Sciences

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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