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

Unfractioned 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 unfractioned heparin. All patients also took oral Aspirin 325 mg/day and Clopidogrel 450 mg before the procedure. Patients were recommended remaining on Clopidigrel 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

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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 unfractioned 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-chanceller for Research Affairs, Shiraz University of Medical Sciences
Full name of responsible person
Vice-chanceller 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-chanceller 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
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Person responsible for updating data

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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