Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

Comparison in myocardial perfusion between the intracoronary versus intralesional eptifibatide administration during primary percutaneous coronary intervention in acute ST-segment elevation myocardial infarction; A randomized clinical trial

Protocol summary

Summary

Objectives: This study aims to comparison of Eptifibatide localized injection and intracoronary injection on the myocardial perfusion improvement and its outcomes. Design:The study is a randomized clinical trial,That will be done for 60 patients with thrombotic AMI. Setting and conduct: The patients will be undergoing percutaneous coronary intervention (PCI) and will be randomly(by using random number table method) dived into two equal number groups. Inclusion criteria: Diagnosis of ST elevation myocardial infarction as defined by chest pain suggestive for myocardial ischemia for at least 30 minutes before hospital admission; these patients should also have three or more thrombus burden grade on the angiography; undergoing PCI; The consent of patients or their families to participate in the study; insensitivity to Eptifibatide. Exclusion criteria: Rescue PCI after thrombolytic therapy; Contraindications for antiplatelet; thrombocytopenia; recent stroke (less than 6 months) and cardiogenic shock. Intervention: The first group will be receiving two bolus doses (180 Microgram / kilogram) of Eptifibatide through guiding catheter. The second group will be receiving the same bolus doses through export aspiration catheter into the coronary lesion directly. Main outcome measures variables: Thrombolysis in myocardial infarction flow, myocardial blush grade and no-reflow phenomenon will primary end points. Secondary end points will pre and post-procedure cardiac arrhythmia, in-hospital mortality, adverse effects, reinfection, pre-discharge ventricular systolic function and re hospitalization and mortality after 6 month follow up.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016122722134N4**
Registration date: **2017-01-07, 1395/10/18**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-01-07, 1395/10/18

Registrant information

Name
Mahtab Keshvari
Name of organization / entity
Cardiovascular Institution
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2016-05-22, 1395/03/02

Expected recruitment end date

2016-08-23, 1395/06/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison in myocardial perfusion between the intracoronary versus intralesional eptifibatide administration during primary percutaneous coronary intervention in acute ST-segment elevation myocardial infarction; A randomized clinical trial

Public title
Comparison in myocardial perfusion between the intracoronary versus intralesional eptifibatide administration in acute myocardial infarction

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Diagnosis of ST elevation myocardial infarction (STEMI) as defined by chest pain suggestive for myocardial ischemia for at least 30 minutes before hospital admission and symptoms onset time was less than 12 hours with 1 mm ST segment elevation in 2 or more contiguous leads (for V1-V3 ST elevation was 2 mm) simultaneously; These patients should also have three or more thrombus burden grade on the angiography. Thrombus burden was graded (G) as G0 = no thrombus, G1 = possible thrombus, G2 = small (greatest dimension ≤ 1/2 vessel diameter), G3 = moderate (> 1/2 but < 2 vessel diameter), G4 = large (≥ 2 vessel diameter), G5 = unable to assess TB due to vessel occlusion; undergoing PCI; The consent of patients or their families to participate in the study; insensitivity to Eptifibatide Exclusion criteria: Rescue PCI after thrombolytic therapy; Contraindications for antiplatelet such as bleeding disorder including gastrointestinal bleeding, hematuria, or known any bleeding tendency; thrombocytopenia (Platelet count<100.000/cm3); recent stroke (less than 6 months) and cardiogenic shock

Age
No age limit

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single 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 Isfahan University of Medical Sciences

Street address
Hezar jirib St.

City
Isfahan

Postal code
8187698191

Approval date
2016-05-18, 1395/02/29

Ethics committee reference number
IR.MUI.REC.1395.2.395420

Health conditions studied

1

Description of health condition studied
cardiovascular disease

ICD-10 code
I20-I25

ICD-10 code description
Certain current complications following acute myocardial infarction

Primary outcomes

1

Description
Thrombolysis in myocardial infarction (TIMI) flow

Timepoint
Before discharge, re hospitalization and after 6 month follow up

Method of measurement
TIMI flow grading

2

Description
myocardial blush grade (MBG)

Timepoint
Before discharge, re hospitalization and after 6 month follow up

Method of measurement
Myocardial blush grading

3

Description
no-reflow phenomenon

Timepoint
Before discharge, re hospitalization and after 6 month follow up

Method of measurement
TIMI flow grading and Myocardial blush grading

Secondary outcomes

1

Description
Re myocardial infarction
Timepoint
Before discharge, re hospitalization and after 6 month follow up
Method of measurement
ECG

2

Description
Heart failure
Timepoint
during hospitalization
Method of measurement
Eco cardiography

3

Description
arrhythmia
Timepoint
Before discharge, re hospitalization and after 6 month follow up
Method of measurement
ECG

4

Description
Ventricular systolic function
Timepoint
Before discharge, re hospitalization and after 6 month follow up
Method of measurement
Eco cardiography

Intervention groups

1

Description
In group I, before performing PCI, if caught thrombosis in (180 micrograms per kilogram) coronary arteries, patients received two boluses of eptifibatide through the guiding catheter in the infarct-related
Category
Treatment - Drugs

2

Description
In group II or intralesional administration group boluses of eptifibatide(180 micrograms per kilogram) is administered through the export aspiration catheter into the lesion of infarct-related artery
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Chamran Cardiology Hospital
Full name of responsible person
Dr. Hassan Shamiran
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Iran, Isfahan, Chamran Cardiology Hospital, Salman-e-Farsi
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Isfahan University of Medical Sciences
Full name of responsible person
Dr. Mehdi Nematbakhsh
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Hezar Jerib Ave., Azadi sqr., Isfahan University of Medical Science, Isfahan, Iran
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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
Vice Chancellor for research of Isfahan 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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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