

# 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 913 781 0322

##### Email address

mkeshvari@crc.mui.ac.ir

#### 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  $\leq$  1/2 vessel diameter), G3 = moderate ( $>$  1/2 but  $<$  2 vessel diameter), G4 = large ( $\geq$  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/cm<sup>3</sup>); 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

##### Street address

Iran, Isfahan, Chamran Cardiology Hospital, Salman-e-Farsi

##### City

Isfahan

## 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

##### Street address

Hezar Jerib Ave., Azadi sqr., Isfahan University of Medical Science, Isfahan, Iran

##### City

Isfahan

#### 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

##### Name of organization / entity

Isfahan University of Medical Sciences

##### Full name of responsible person

Abdulattef Ghazal

##### Position

Cardiology Interventional Fellowship

##### Other areas of specialty/work

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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*