

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparing the effect of receiving only bolus dose Eptifibatide with bolus plus infusion strategy on bleeding complications and consequences after Percutaneous Coronary Intervention (PCI) on Myocardial Infarct (MI) patients

#### Protocol summary

##### Summary

Aim of this study: Comparing the effect of only bolus Eptifibatide with bolus plus infusion form of Eptifibatide on bleeding complications after PCI on MI patients  
Inclusion criteria: MI patients who are candidate for angioplasty and PCI Exclusion criteria: having sensitivity to Eptifibatide or any contraindication for using this medication Patients are randomly divided in to two groups. the first group is received 180 mcg/kg Eptifibatide before PCI in bolus form from a peripheral vein during 8 minutes. The second group is received 180 mcg/kg Eptifibatide before PCI in bolus form from peripheral vein during 8 minutes and after PCI they are received infusion of 2 mcg/kg/min Eptifibatide for 10 hours. After intervention the incidence of bleeding complications and hematoma is evaluated and compared between two groups.

#### General information

##### Acronym

No

##### IRCT registration information

IRCT registration number: **IRCT2017071935183N1**

Registration date: **2017-08-07, 1396/05/16**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-08-07, 1396/05/16

##### Registrant information

###### Name

hasan shemirani

##### Name of organization / entity

isfahan university of medical science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3668 3407

##### Email address

shemirani@med.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Isfahan university of medical science

##### Expected recruitment start date

2017-07-23, 1396/05/01

##### Expected recruitment end date

2018-02-20, 1396/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparing the effect of receiving only bolus dose Eptifibatide with bolus plus infusion strategy on bleeding complications and consequences after Percutaneous Coronary Intervention (PCI) on Myocardial Infarct (MI) patients

##### Public title

Comparing the effect of only bolus Eptifibatide with bolus plus infusion form of Eptifibatide on bleeding complications and consequences on myocardial infarct patients

##### Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria were as followed: 1) age more than 18 years, 2)having elevation in Troponin enzyme level, 3) having electrocardiogram changes due to infarction, 4)candidate for angioplasty and percutaneous coronary intervention, 5) having no contraindication for administrating Eptifibatide, 6) patient's willingness to participate in this study Exclusion criteria were as followed:1) Patient's unwillingness to continue his/ her participation, 2)history of stroke, 3)treating with anti coagulant medications, 4)using medications that has interaction with Eptifibatide, 5) have not experience PCI, 6)have experienced thrombectomy, 7) having sensitivity to Eptifibatide, 8) having uncontrolled hypertension, 9) dialysis patients

### Age

From **18 years** old to **90 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **176**

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Not blinded

### Blinding description

### Placebo

Not used

### Assignment

Parallel

### Other design features

No

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Isfahan university of medical science

##### Street address

isfahan, hezar jarib street, isfahan university of medical sciene

##### City

isfahan

##### Postal code

#### Approval date

2010-08-20, 1389/05/29

#### Ethics committee reference number

395717

## Health conditions studied

### 1

#### Description of health condition studied

myocardial infarction

#### ICD-10 code

I21

#### ICD-10 code description

E1, E2, E3, E4, E9

## Primary outcomes

### 1

#### Description

incidence of hematoma

#### Timepoint

immediately after intervention, 24, 48,72 and 96 hours after intervention

#### Method of measurement

observation

### 2

#### Description

incidence of bleeding

#### Timepoint

immediately after intervention, 24, 48,72 and 96 hours after intervention

#### Method of measurement

observation

## Secondary outcomes

### 1

#### Description

needs for additional coronary intervention

#### Timepoint

one week after intervention

#### Method of measurement

physical examination

### 2

#### Description

death

#### Timepoint

one week after intervention

#### Method of measurement

observation

## Intervention groups

### 1

#### Description

the first group is received a bolus dose of 180 mcg/kg Eptifibatide (Integrilin company)from peripheral vein during 8 minutes, immediately before PCI and after that PCI is done.After PCI. all patients received 75 mg

clopidogrel for every 12 hours as a routine treatment.

**Category**

Treatment - Drugs

**2**

**Description**

Patients in the second group received routine treatment in addition with 10-hours infusion of 2 mcg/kg/min Eptifibatide with maximum dose of 15 mcg/hour and if patients creatinine clearance < 50 mg/min, about 1 mcg/kg/min of Eptifibatide were infused and if patients had creatinine > 4, they were excluded from study. All patients were received 75 mg clopidogrel every 12 hours as a routine treatment

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

shahid chamran hospital

**Full name of responsible person**

Ali eghbal

**Street address**

isfahan, bozorgmehr brdge, abshare sevom street, shahid chamran hospital

**City**

isfahan

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

isfahan university of medical science

**Full name of responsible person**

Mehdi Nematbakhsh

**Street address**

isfahan, hezar jarib street, isfahan university of medical science

**City**

isfahan

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

isfahan university of medical science

**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 science

**Full name of responsible person**

hasan shemirani

**Position**

cardiologist, assistant professor

**Other areas of specialty/work**

**Street address**

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**Web page address**

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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*