

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### A comparison of complication & major cardiovascular events of bolus eptifibatide versus bolus plus infusion of eptifibatide in Primary PCI in patients with acute ST-elevation myocardial infarction

#### Protocol summary

##### Study aim

The bleeding complication and in-hospital major cardiovascular events of bolus eptifibatide versus bolus plus the infusion of eptifibatide in patients undergoing primary PCI.

##### Design

This is a randomized double-blind clinical trial. The sample size is 163 patients in each group. The intervention group will receive a 2 mcg/kg/min infusion of eptifibatide of a single vial of 75 mg /100 ml (Short term protocol). The control group will receive the same amount and duration of normal saline.

##### Settings and conduct

The study will be done in Shahid Rajaei Hospital Karaj, Iran.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with Ischemic heart attack symptoms that last more than 20 minutes and less than 12 hours with 1mm ST elevation in 2 limb leads or 2mm ST elevation in 2 precordial leads who are candidates for primary PCI intervention. Exclusion criteria: Not acceptance of informed consent. History of sensitivity to eptifibatide, heparin, or aspirin. Recent treatment with warfarin (INR>2), fibrinolytic or other IIb/IIIa inhibitors. Platelet <100000/mcL. Known bleeding disorder. History of ischemic cerebrovascular accident in previous 30 days. History of hemorrhagic cerebrovascular accident. Abnormal bleeding within 30 days. Major surgery in previous 6 weeks. Renal failure with hemodialysis. Uncontrolled hypertension (SBP>200mmHg, or DBP>110mmHg).

##### Intervention groups

The intervention group will receive eptifibatide bolus without the infusion. The Control group will receive eptifibatide bolus with placebo infusion.

##### Main outcome variables

Presence of vascular or bleeding complications

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20110512006463N3**

Registration date: **2021-03-17, 1399/12/27**

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

Last update: **2021-03-17, 1399/12/27**

Update count: **0**

##### Registration date

2021-03-17, 1399/12/27

##### Registrant information

##### Name

Mehdi Mousavi

##### Name of organization / entity

Alborz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 26 3457 0030

##### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-04-01, 1397/01/12

##### Expected recruitment end date

2021-03-20, 1399/12/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

A comparison of complication & major cardiovascular events of bolus eptifibatide versus bolus plus infusion of eptifibatide in Primary PCI in patients with acute ST-elevation myocardial infarction

### Public title

Bolus eptifibatide versus bolus plus infusion

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Patients with symptoms of ischemic heart attack that last no longer than 12 hours with 1 mm ST elevation in at least 2 limb leads or 2 mm ST elevation in at least 2 precordial leads who are candidates for Primary PCI intervention.

#### Exclusion criteria:

Not acceptance of informed consent History of sensitivity to eptifibatide, heparin or aspirin Recent treatment with warfarin (INR>2), fibrinolytics or other IIb/IIIa inhibitors Platelet <100000/mcL Known bleeding disorder History of ischemic cerebrovascular accident in previous 30 days History of hemorrhagic cerebrovascular accident Abnormal bleeding in recent 30 days. Major surgery in previous 6 weeks Renal failure with dependency to hemodialysis Uncontrolled hypertension (SBP>200mmHg, or DBP>110mmHg)

### Age

From **18 years** old

### Gender

Both

### Phase

3

### Groups that have been masked

- Participant
- Outcome assessor

### Sample size

Target sample size: **163**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Block randomization was done using the website of: "https://www.sealedenvelope.com/simple-randomiser/v1/lists" The treatment group was put in pockets to be used during the study and the study group was determined according to the content of pockets

### Blinding (investigator's opinion)

Double blinded

### Blinding description

For blinding, the control group received normal saline as the placebo with the same volume and time duration as the intervention group. Patients are blinded to the received medication. The outcome assessor will be blinded to the treatment allocation group

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Alborz Medical School

##### Street address

Alborz university of medical sciences- North Taleghani Blvd, Karaj, Iran

##### City

karaj

##### Province

Alborz

##### Postal code

3149779453

#### Approval date

2020-10-10, 1399/07/19

#### Ethics committee reference number

IR.ABZUMS.REC.1399.221

## Health conditions studied

### 1

#### Description of health condition studied

Acute ST elevation myocardial infarction

#### ICD-10 code

I21.3

#### ICD-10 code description

ST elevation (STEMI) myocardial infarction of unspecified site

### 2

#### Description of health condition studied

Acute ST elevation myocardial infarction

#### ICD-10 code

I21.0

#### ICD-10 code description

ST elevation (STEMI) myocardial infarction of anterior wall

### 3

#### Description of health condition studied

Acute ST elevation myocardial infarction

#### ICD-10 code

I21.1

#### ICD-10 code description

ST elevation (STEMI) myocardial infarction of inferior wall

### 4

#### Description of health condition studied

Acute ST elevation myocardial infarction

#### ICD-10 code

I21.2

**ICD-10 code description**

ST elevation (STEMI) myocardial infarction of other sites

**Primary outcomes**

**1**

**Description**

Vascular or bleeding complication

**Timepoint**

During in-hospital admission

**Method of measurement**

Questionnaire and physical exam

**Secondary outcomes**

**1**

**Description**

Death

**Timepoint**

2 days and 6 months after intervention

**Method of measurement**

Questionnaire, Electronic file

**2**

**Description**

Myocardial infarction

**Timepoint**

2 days and 6 months after intervention

**Method of measurement**

ECG and increase in CKMB

**3**

**Description**

Need for target lesion revascularization (TLR)

**Timepoint**

2 days and 6 months after intervention

**Method of measurement**

Questionnaire, Electronic file

**4**

**Description**

Need for target vessel revascularization (TVR)

**Timepoint**

2 days and 6 months after intervention

**Method of measurement**

Questionnaire, Electronic file

**5**

**Description**

Need for coronary artery bypass graft (CABG)

**Timepoint**

2 days and 6 months after intervention

**Method of measurement**

Questionnaire, Electronic file

**6**

**Description**

Cerebrovascular accidents

**Timepoint**

2 days and 6 months after intervention

**Method of measurement**

Questionnaire, Electronic file

**Intervention groups**

**1**

**Description**

Intervention group will receive 2 bolus doses of eptifibatide (Merk) with dose of 180mcg/kg with 10 minute interval. Then they will receive 2mcg/kg/min of eptifibatide infusion; totally 1 vial of 75mg/cc (short term protocol)

**Category**

Treatment - Drugs

**2**

**Description**

Control group: will receive 2 bolus doses of eptifibatide (Merk) with a dose of 180mcg/kg with a 10-minute intervals. Then they will receive normal saline as the placebo with the same volume and time duration as the intervention group.

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Shahid Rajae hospital, Karaj, Iran

**Full name of responsible person**

Dr. Mehdi Musavi

**Street address**

R and D unit, Shahid Rajaei hospital, Shahid Rajei Ave, Karaj, Iran

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## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Deputy of research and technology of Alborz  
University of Medical Sciences

**Full name of responsible person**

Dr.Mohamad Noorisepehr

**Street address**

Deputy of research and technology of Alborz  
university of medical sciences, Safarian Av, Golshahr,  
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research@abzums.ac.ir

**Web page address**

<https://research.abzums.ac.ir>

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Deputy of research and technology of Alborz University  
of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

Academic

## Person responsible for general inquiries

**Contact****Name of organization / entity**

Alborz University of Medical Sciences

**Full name of responsible person**

Dr. Fatemeh Sehati

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Cardiology

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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Specialist

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**Other areas of specialty/work**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

**Title and more details about the data/document**

Data after deidentification

**When the data will become available and for how long**

After publishing the article

**To whom data/document is available**

Investigatores

**Under which criteria data/document could be used**

Email to corresponding author

**From where data/document is obtainable**

Corresponding author

**What processes are involved for a request to access data/document**

Email

**Comments**