Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 Rajaee 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 IIbIIIa 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

mmoosavi@razi.tums.ac.ir

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), fibrinolythics or other IIbIIIa 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 admision

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

City

Karaj

Province

Alborz

Postal code

3197635141

Phone

+98 26 3457 0030

Fax

+98 26 3455 4484

Email

moosavi_m_md@yahoo.com

Web page address

https://rajaei.abzums.ac.ir

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, Karaj, Iran

City
Karaj

Province
Alborz

Postal code
3198764653

Phone
+98 26 3464 3705

Fax
+98 26 3455 4484

Email
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

Street address
R and D unit, Shahid Rajaei Hospital, Shahid Rajaei Ave, Karaj, Iran

City
Karaj

Province
Alborz

Postal code
3197635141

Phone
+98 26 3457 0030

Fax
+98 26 3455 4484

Email
F_sehati@yahoo.com

Web page address

Person responsible for scientific 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

Street address
R and D unit, Shahid Rajaei Hospital, Shahid Rajai Ave, Karaj, Iran

City
Karaj

Province
Alborz

Postal code
3197635141

Phone
+98 26 3457 0030

Fax
+98 26 3455 4484

Email
f_sehati@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Alborz University of Medical Sciences

Full name of responsible person
Mehdi Mousavi

Position
Specialist

Latest degree
Specialist

Other areas of specialty/work
Cardiology

Street address
R and D unit, Shahid Rajai Hospital, Shahid Rajai Ave,

Karaj, Iran
City
Karaj
Province
Alborz
Postal code
3197635141
Phone
+98 264570030
Fax
+98 26 3455 4484
Email
moosavi_m_md@yahoo.com
Web page address

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 correspounding author
From where data/document is obtainable
Corresponding author
What processes are involved for a request to access data/document
Email
Comments