

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

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

City

isfahan

Postal code

Phone

+98 31 3260 0961

Fax

+98 32600961

Email

shemirani@med.mui.ac.ir

Web page address

https://mui.ac.ir/

Person responsible for scientific inquiries

Contact

Name of organization / entity

isfahan university of medical science

Full name of responsible person

hasan shemirani

Position

cardiologist

Other areas of specialty/work

Street address

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

City

isfahan

Postal code

Phone

+98 31 3260 0961

Fax

+98 31 3260 0961

Email

shemirani@med.mui.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

isfahan university of medical science

Full name of responsible person

hasan shemirani

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Street address

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

City

isfahan

Postal code

Phone

+98 31 3260 0961

Fax

Email

shemirani@med.mui.ac.ire

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