

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Comparison of cardiovascular outcomes (repeated infarction, infarct size, hemorrhage, and death) of intracoronary abciximab or intravenous eptifibatide administration during percutaneous coronary intervention of ST-segment elevation myocardial infarction

Protocol summary

Summary

The objective of this study is to compare the efficacy of intracoronary abciximab and intravenous eptifibatide in percutaneous coronary intervention of myocardial infarction with ST segment elevation. Inclusion criterion is acute myocardial infarction with ST segment elevation according to clinical, laboratory, and ECG findings. Exclusion criteria are presentation after 12 hours of symptoms onset, those with spastic angina (resolution of ST segment elevation and alleviation of symptoms after intravenous nitroglycerine administration), those with non-ST segment elevation myocardial infarction, history of stroke or intracerebral hemorrhage, contraindication for platelet administration, and cardiogenic shock. Forty STEMI patients were randomized to either intracoronary abciximab or intravenous eptifibatide. Abciximab dosage was 0.25 µg/kg. In another group two boluses (each 180 µg/kg) of eptifibatide were administered every 10 minutes. Outcomes assessed are infarct size, myocardial reperfusion, TIMI grade after intervention, repeated infarction, hemorrhage, and death.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012081310573N1**
Registration date: **2012-09-09, 1391/06/19**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-09-09, 1391/06/19

Registrant information

Name

Habibollah Saadat

Name of organization / entity

Cardiovascular Research Center, Modarres Hospital,
Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2208 3106

Email address

h_saadat@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Cardiovascular Research Center, Shahid Beheshti
University of Medical Sciences, Tehran, Iran

Expected recruitment start date

2011-08-27, 1390/06/05

Expected recruitment end date

2012-03-17, 1390/12/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of cardiovascular outcomes (repeated infarction, infarct size, hemorrhage, and death) of intracoronary abciximab or intravenous eptifibatide administration during percutaneous coronary intervention of ST-segment elevation myocardial infarction

Public title

Efficacy of intracoronary abciximab in percutaneous coronary intervention

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: ST elevation myocardial infarction (MI)

Exclusion criteria: patients presenting with ST-elevation myocardial infarction after 12 hours from symptoms

onset; patients presenting with vasospastic angina (determined by resolution of ST segment elevation, and relief of symptoms after intravenous administration of nitroglycerin); patients presenting with non-ST elevation MI; contraindications for antiplatelets such as bleeding disorder including gastrointestinal bleeding, hematuria, or any known bleeding tendency either inherited or acquired; thrombocytopenia (Platelet count less than 100.000 per microliter; recent (less than 6 months) stroke; intracranial hemorrhage at any time in patient's life or any known intracranial malformation; cardiogenic shock; left bundle branch block changes on ECG.

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

N/A

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Cardiovascular Research Center, Shahid Beheshti
University of Medical Sciences

Street address

Saadat-Abad Ave.

City

Tehran

Postal code

Approval date

2011-08-25, 1390/06/03

Ethics committee reference number

154/MT

Health conditions studied

1

Description of health condition studied

ST-segment elevation myocardial infarction

ICD-10 code

I21

ICD-10 code description

myocardial infarction specified as acute or with a stated duration of 4 weeks (28 days) or less from onset

Primary outcomes

1

Description

Infarct size

Timepoint

Day 2

Method of measurement

Area under the curve of the cardiac creatine kinase-MB release

2

Description

Myocardial reperfusion

Timepoint

First day

Method of measurement

resolution of ST segment elevation

3

Description

Reinfarction

Timepoint

Days 1 to 7

Method of measurement

Recurrent symptoms suggestive of ischemia with new ST-segment elevation and/or elevation of serum cardiac markers levels

Secondary outcomes

empty

Intervention groups

1

Description

In control group, two boluses of eptifibatide (each 180 microgram per kilogram body weight) were administered intravenously 10 minutes apart during percutaneous coronary intervention.

Category

Treatment - Drugs

2

Description

In intervention group, abciximab with a dosage of 0.25 microgram per kilogram body weight was administered into coronary arteries via microcatheter during percutaneous coronary intervention.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Cardiology Department, Modarres Hospital, Tehran, Iran

Full name of responsible person

Habibollah Saadat

Street address

Saadat-Abad Ave.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Cardiovascular Research Center, Shahid Beheshti University of Medical sciences

Full name of responsible person

Morteza Safi

Street address

Modarres Hospital, Saadat-Abad Ave.

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Cardiovascular Research Center, Shahid Beheshti 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

Shahid Beheshti Cardiovascular Research Center

Full name of responsible person

Mohammad Hassan Namazi

Position

Associated Professor of Cardiology

Other areas of specialty/work

Street address

Cardiology Department, Modarres Hospital, Saadat-Abad Ave.

City

Tehran

Postal code

Phone

+98 21 2208 3106

Fax

Email

namazimh@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti Cardiovascular Research Center

Full name of responsible person

Habibollah Saadat

Position

Associated professor of Cardiology

Other areas of specialty/work

Street address

Cardiology Department, Modarres Hospital, Saadat-Abad Ave.

City

Tehran

Postal code

Phone

+98 21 2208 3106

Fax

Email

h_saadat@sbmu.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Cardiovascular Research Center

Full name of responsible person

Habibollah Saadat

Position

Associated Professor of Cardiology

Other areas of specialty/work

Street address

Cardiology Department, Modarres Hospital, Saadat-Abad Ave.

City

Tehran

Postal code

Phone

+98 21 2208 3106

Fax

Email

h_saadat@sbmu.ac.ir

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