

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

A Comparison of Intracoronary with Intravenous Administration of Integrilin During Primary Percutaneous Coronary Intervention in Patients with acute ST-Elevation Myocardial Infarction: Clinical Outcomes

Protocol summary

Summary

Purpose: Treatment Study Design: Randomizedm, Double-blinded, Single center, Clinical Trial Inclusion Criteria: an acute coronary syndrome with the indication for cardiac catheterization being ST-elevation myocardial infarction; coronary artery disease with a visually estimated stenosis of at least 75% in at least 1 epicardial vessel suitable for stenting; age \geq 18 years; Exclusion Criteria: multivessel PCI at the time of the index procedure or planned PCI within 30 days of the index procedure; severe coronary calcification; unprotected left main stenosis \geq 50%; target lesion in a saphenous vein graft; acute ST-elevation myocardial infarction with a primary PCI strategy; previous stenting at the target lesion; target lesion in an occluded vessel; and a contraindication to GP IIb/IIIa inhibitor therapy
Population: Patients with Acute STEMI admitted in Bu Ali Hospital, Qazvin undergoing Primary PCI in time of study who has inclusion criteria Sample volume: 70 samples
Intervention: Intracoronary vs. intravenous administration of integrilin during Primary PCI Time of Intervention: Within Primary PCI Clinical Primary end pint: Microvascular perfusion assessment by TPG, TFG and cTFC

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012090510751N1**
Registration date: **2014-06-23, 1393/04/02**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-06-23, 1393/04/02

Registrant information

Name

Amir Esfandi

Name of organization / entity

Qazvin University Of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor For Research - Medical School - QUMS

Expected recruitment start date

2012-09-22, 1391/07/01

Expected recruitment end date

2014-06-22, 1393/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Comparison of Intracoronary with Intravenous Administration of Integrilin During Primary Percutaneous Coronary Intervention in Patients with acute ST-Elevation Myocardial Infarction: Clinical Outcomes

Public title

Intracoronary Integrilin Administration in Patient with Acute ST-Elevation Myocardial Infarction undergoing Primary PCI

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: an acute coronary syndrome with the indication for cardiac catheterization being ST-elevation myocardial infarction; coronary artery disease with a visually estimated stenosis of at least 75% in at least 1 epicardial vessel suitable for stenting; age \geq 18 years; negative pregnancy test in women of childbearing potential; informed consent for participation in the trial
Exclusion Criteria: multivessel PCI at the time of the index procedure or planned PCI within 30 days of the index procedure; severe coronary calcification; unprotected left main stenosis $>$ 50%; target lesion in a saphenous vein graft; acute ST-elevation myocardial infarction after a primary PCI strategy; previous stenting at the target lesion; target lesion in an occluded vessel; deep vein thrombosis; presence of an inferior vena cava filter; a contraindication to GP IIb/IIIa inhibitor therapy (Hypersensitivity to eptifibatide or any component of the product; active abnormal bleeding within the previous 30 days or a history of bleeding diathesis; history of stroke within 30 days or a history of hemorrhagic stroke; severe hypertension (systolic blood pressure $>$ 200 mm Hg or diastolic blood pressure $>$ 110 mm Hg) not adequately controlled on antihypertensive therapy; major surgery within the preceding 6 weeks; current or planned administration of another parenteral GP IIb/IIIa inhibitor; dependency on hemodialysis).

Age

From **18 years** old to **139 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Regional Council of Ethics in Researches in Qazvin
University of Medical Sciences

Street address

Qazvin University of Medical Sciences - Shahid

Bahonar Buldv. - Qazvin

City

Qazvin

Postal code

59811-34197

Approval date

2012-11-27, 1391/09/07

Ethics committee reference number

20/5258/s

Health conditions studied

1

Description of health condition studied

Acute myocardial infarction

ICD-10 code

I21

ICD-10 code description

Acute myocardial infarction

2

Description of health condition studied

Recurrent Myocardial Infarction

ICD-10 code

I22

ICD-10 code description

Subsequent myocardial infarction

Primary outcomes

1

Description

TIMI Flow Grade

Timepoint

Before and After Primary PCI

Method of measurement

Antrograde Coronary Perfusion assessed by Coronary Angiography

2

Description

TIMI Perfusion Grade

Timepoint

Before and After Primary PCI

Method of measurement

Antrograde Coronary Perfusion assessed by Coronary Angiography based on TPG classification

3

Description

TIMI Frame Count

Timepoint

Before and After Primary PCI

Method of measurement

Angiographic frame count of contrast from injection to filling the coronary artery which underwent Primary PCI

Secondary outcomes

1

Description

Adverse Bleeding Event

Timepoint

From Primary PCI to Patient Discharge

Method of measurement

Incidence of Bleeding event during hospitalization based on International Bleeding classification

2

Description

Change in Ejection Fraction

Timepoint

Before Primary PCI and 5 days after

Method of measurement

By Echocardiography

3

Description

ST Segment Elevation Resolution

Timepoint

Before Primary PCI and 60 minutes after

Method of measurement

Single-lead ST elevation (ST-E) recovery (percent reduction in ST-E from baseline to post-PCI ECG in the lead with maximum baseline ST-E)

4

Description

Thrombocytopenia

Timepoint

Before Primary PCI and 3 hours after

Method of measurement

Reduction of Platelet in PBS over 50% or below 100000 per ml

Intervention groups

1

Description

In Intracoronary arm (intervention), 180 microgram per Kg of patient's body weight administer, 2 bolus 10 minutes apart, first before pass the guidewire and second bolus after passing the guidewire, as intracoronary injection. Infusion of 2 microgram per kg per minute of integrilin will be continued intravenously up to 12 hours after procedure.

Category

Treatment - Drugs

2

Description

in IV arm (control), 180 microgram per Kg of patient's body weight of integrilin will be injected intravenously, 10 minutes apart, before and after passing the

guidewire. Infusion of 2 microgram per kg per minute of integrilin will be continued intravenously up to 12 hours after procedure.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Bu Ali Sina Hospital

Full name of responsible person

Amir Esfandi

Street address

Qazvin - Buali Sina St. - Buali Sina Hospital

City

Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

QUMS Deputy for Research

Full name of responsible person

Mahnaz Abbasi

Street address

Room No. 201 - 2nd floor - Faculty of Medicine - QUMS

City

Qazvin

Grant name

Grant code / Reference number

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

Yes

Title of funding source

QUMS Deputy for Research

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

Qazvin University of Medical Sciences

Full name of responsible person

Amir Esfandi

Position

Medical Student

Other areas of specialty/work**Street address**

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Full name of responsible person

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Qazvin University Of Medical Sciences

Full name of responsible person

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Position

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00

Fax**Email**

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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