

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Comparison of Outcomes following Deferred Versus Immediate Stenting in Patient with ST Elevation Myocardial Infarction Admitted to Emergency Department of Heshmat Hospital at 2015 - 2016

Protocol summary

Summary

This study will be conducted on 57 patients with acute myocardial infarction with elevated ST. Inclusion criteria: the duration of symptoms more than six hours, anomalies of involved coronary artery including blocked artery in primary angiography primary perfusion, high volume of thrombosis, high length of lesion (more than 24 mm) , small diameter of vessels (less than 5.2 mm), and exclusion criteria include the lack of normal coronary flow. Patients will be given common treatment includes aspirin 300 mg and clopidogrel 600 mg and heparin 5,000 units on admission. After the restoration of blood flow the informed consent of patients will be taken. Background and clinical variables, including diabetes, hypertension and will be measured. The subjects were randomly allocated into two groups using block randomization. The first group which is characterized by the Code A, stenting will be done is performed immediately after common treatment. In Group B (Group deferred or delayed) stenting will be done at least 12 to 168 hours after the initial treatment. 12 to 168 hours interval time has been selected based on the intravenous treatment time necessity and the patient's condition and the patients of deferred group will receive all treatment protocols for delayed group including inhibitor of glycoprotein IIb / IIIa intravenous infusion and subcutaneous injection of enoxaparin for 24 hours. Blood pressure, electrocardiography and clinical symptoms during procedure and before stenting will be monitored. After completing PCI, patients undergoing secondary preventive common treatment

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015120125327N1**

Registration date: **2016-01-10, 1394/10/20**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-01-10, 1394/10/20

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research Guilan University of Medical Sciences

Expected recruitment start date

2016-03-20, 1395/01/01

Expected recruitment end date

2017-03-21, 1396/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Outcomes following Deferred Versus

Immediate Stenting in Patient with ST Elevation
Myocardial Infarction Admitted to Emergency
Department of Heshmat Hospital at 2015 - 2016

2015-11-15, 1394/08/24
Ethics committee reference number
IR.GUMS.REC.13940329

Public title

The outcomes of immediate and deferred stenting in primary angioplasty

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: the duration of symptoms more than six hours, anomalies of involved coronary artery including blocked artery in primary angiography primary perfusion (TIMI0.1) , high volume of thrombosis, high length of lesion (more than 24 mm , small diameter of vessels (less than 5.2 mm) , clinical signs of acute injury of micro-vascular after primary perfusion (with increasing ST more than 50%) Exclusion criteria include the lack of normal coronary flow (TIMI3) after primary perfusion treatment with thrombus aspiration with or without balloon angioplasty, cardiogenic shock and inability to obtain informed consent.

Age

From **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **57**

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**

Ethics committee of Guilan University of Medical Sciences

Street address

Next to Iran Radiator Building, Gaz Square, Rasht

City

Rasht

Postal code**Approval date****Health conditions studied****1****Description of health condition studied**

Acute myocardial infarction

ICD-10 code

I21.0 , I2

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**

no/slow reflow

Timepoint

In the first group (immediate) measured immediately after angiography

Method of measurement

By Echocardiography. This outcome has three degrees : lack of blood flow (TIMI0), incomplete filling (TIMI1), establish low blood flow but with complete filling (TIMI2) in involved coronary artery during or at the end of PCI

Secondary outcomes**1****Description**

The consequences of electrocardiographic

Timepoint

One hour after treatment compared _ basic ECG, before reperfusion

Method of measurement

By electrocardiogram Complete resolution of ST elevation 70% <, relative 30-70% or non-occurrence > 30 %

2**Description**

The consequences of Angiographic

Timepoint

At the end of the first procedure as prospective

Method of measurement

By Angiography, stent dimensions are compared with real stent at the second procedure by the same operator

3**Description**

The consequences of Echocardiography

Timepoint

Before the first procedure and discharge

Method of measurement

Based on wall motion score index

Intervention groups

1

Description

Stenting immediately after treatment with aspirin 300 mg and clopidogrel 600 mg heparin 5000 U

Category

Treatment - Surgery

2

Description

Deferred Group: stenting at least 12 to 168 hours after the primary treatment

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Heshmat Hospital

Full name of responsible person

Dr Majid Chinicar

Street address

Heshmat Hospital, 15 khordad St. , Rasht, Guilan, Iran

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research Guilan University of Medical Sciences

Full name of responsible person

Abtin Heidarzadeh (Specialist)

Street address

Next to Iran Radiator Building, Gaz Square, Rasht

City

Rasht

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research Guilan 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

Guilan University of Medical Sciences

Full name of responsible person

Nozar Sotoudeh Foumani

Position

Resident of Cardiology

Other areas of specialty/work

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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