

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Comparison of the efficacy of intracoronary and intravenous Eptifibatide and intracoronary Reteplase on coronary blood flow in patients undergoing PPCI at Dr.Heshmat hospital during 2017-2018 (Randomized clinical trial study)

Protocol summary

Study aim

Determining the Effectiveness of intracoronary and intravenous Eptifibatide and Intracoronary Reteplase on coronary artery blood flow in patients with primary percutaneous coronary intervention

Design

In this study, 160 patients who had the first acute myocardial infarction with ST elevation and who were referred to Dr.Heshmat Hospital in Rasht and who are candidates for primary angioplasty are selected. Participants are randomly assigned to three intervention groups and a control group.

Settings and conduct

This study will be conducted in patients referring to Dr.Heshmat heart hospital in Rasht , who are undergoing primary angioplasty.

Participants/Inclusion and exclusion criteria

patients 18 to 80 years of age who had STEMI for the first time and less than 12 hours of onset of symptoms has spent, and the decision to perform primary PCI is taken for them will enter the study. Patients having normal blood flow in angiography or requiring coronary artery bypass surgery are excluded from the study.

Intervention groups

Group 1: Patients who will embeded a stent after thrombosuction. Group 2: Patients who receive 180 microgram / kg of eptifibatide by intracoronary bolus in 10 minutes interval , and then stent is inserted. Group 3: Patients who receive 6 mg intracoronary reteplase after thrombosuction, and then stent is embedded. Group 4: Patients after thrombosuction will receive 180 micrograms per kilogram of intravenous bolus eptifibatide, and then receive infusion in 2 microgram per kilogram per minute for 18 hours.

Main outcome variables

coronary blood flow, left ventricular diastolic dysfunction

change, ST resolution average, average of EF changes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170925036401N1**

Registration date: **2017-12-07, 1396/09/16**

Registration timing: **registered_while_recruiting**

Last update: **2017-12-07, 1396/09/16**

Update count: **0**

Registration date

2017-12-07, 1396/09/16

Registrant information

Name

mostafa zadkamali

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3333 6394

Email address

mzadkamali@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-01, 1396/09/10

Expected recruitment end date

2018-04-19, 1397/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of intracoronary and intravenous Eptifibatide and intracoronary Reteplase on coronary blood flow in patients undergoing PPCI at Dr.Heshmat hospital during 2017-2018 (Randomized clinical trial study)

Public title

effect of eptifibatide and reteplase on primary angioplasty outcomes

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

ischemic tipic chest pain extending more than 30 min, STElevation more than 1 mm in at least 2 leads with the same name, all patients with STEMI candidate for primary PCI, myocardial infarction not extending more than 12 hours, having life expectancy not less than 6 months, consent for participation in the study, age 18 to 80 years, no evidence for prior myocardial infarction, not having contraindications for reteplase or eptifibatide, not having left bundle branch block, not using GPIIb/IIIa in recent two weeks.

Exclusion criteria:

rescue PCI after thrombolytic therapy, emergency CABG, cardiogenic shock, atrial fibrillation TIMI flow grade 3 in primary angiography(ie, having normal blood flow in coronary arteries) simultaneously presence in another intervention study

AgeFrom **18 years** old to **80 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **160****Randomization (investigator's opinion)**

Randomized

Randomization description

random block

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Other

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

the old building of the School of Public Health ,opposite the 17th Shahrivar Hospital, Shahid Siadati Ave,Namjoo Ave ,Rasht Town

City

Rasht

Province

Guilan

Postal code

4188794755

Approval date

2017-11-04, 1396/08/13

Ethics committee reference number

IR.GUMS.REC.1396.304

Health conditions studied**1****Description of health condition studied**

Acute Myocardial Infarction

ICD-10 code

I21

ICD-10 code description

Acute myocardial infarction

Primary outcomes**1****Description**

coronary blood flow

Timepoint

before and after primary PCI

Method of measurement

based on angiographic scale TIMI blush grade

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

left ventricular diastolic dysfunction change

Timepoint

before and after angiography

Method of measurement

according to echocardiographic criteria

2**Description**

ST resolution average

Timepoint

before and 90 minutes after PCI

Method of measurement

based on electrocardiogram

3

Description

average of EF changes

Timepoint

before and 3 to 4 days after angioplasty

Method of measurement

based on echocardiography

Intervention groups

1

Description

Intervention group: Group 1: Patients who have a stent after thrombosuction.

Category

Treatment - Drugs

2

Description

Intervention group: Group 2: Patients who receive 180 microgram per kilogram of intracoronary bolus eptifibatide by interval of 10 minutes and then stent is embedded.

Category

Treatment - Drugs

3

Description

Intervention group: Group 3: Patients who receive 6 mg of intra-coronary reptal after thrombosis, and then inserted into the stent.

Category

Treatment - Drugs

4

Description

Intervention group: Group 4: Patients after thrombosuction will receive 180 microgram per kilogram of intravenous bolus eptifibatide and then receive 2 microgram per kilogram per minute of infusion over 18 hours.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Heshmat heart hospital

Full name of responsible person

dr. mostafa zadkamali

Street address

15 khordad Ave, Next to Gilan Province Management and Planning Organization, Rasht Town

City

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41939-55588

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mzadkamali@gums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Dr. Shadman Nemati

Street address

the old building of the School of Public Health, opposite the 17th Shahrivar Hospital, Namjoo Ave, Shahid Siadati Ave, Rasht

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mhoseinie@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Rasht 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

Rasht University of Medical Sciences

Full name of responsible person

Mostafa Zadkamali

Position

resident of cardiology

Latest degree

Medical doctor

Other areas of specialty/work

Cardiology

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Person responsible for updating data

Contact

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Full name of responsible person

mahbubeh Taleb Jannesar Hoseinie

Position

medical doctor

Latest degree

Medical doctor

Other areas of specialty/work

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Full name of responsible person

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Position

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Email

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available