

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 2026

### Comparison of the efficacy of intracoronary and intravenous Eptifibatide and intracoronary Retaplastase in thrombus aspiration in patients undergoing Primary percutaneous coronary interventions (PPCI); Randomized clinical trial study)

#### Protocol summary

**Study aim**  
**Design**  
**Settings and conduct**  
**Participants/Inclusion and exclusion criteria**  
**Intervention groups**  
**Main outcome variables**

Sciences

**Expected recruitment start date**  
2017-11-21, 1396/08/30  
**Expected recruitment end date**  
2018-04-19, 1397/01/30  
**Actual recruitment start date**  
empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

#### General information

**Reason for update**  
**Acronym**

#### IRCT registration information

IRCT registration number: **IRCT20170925036401N2**  
Registration date: **2017-12-22, 1396/10/01**  
Registration timing: **registered\_while\_recruiting**

Last update: **2017-12-22, 1396/10/01**  
Update count: **0**

#### Registration date

2017-12-22, 1396/10/01

#### Registrant information

**Name**  
mostafa zadkamali  
**Name of organization / entity**  
**Country**  
Iran (Islamic Republic of)  
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#### Recruitment status

**Recruitment complete**

#### Funding source

Deputy of Research of Guilan University of Medical

#### Scientific title

Comparison of the efficacy of intracoronary and intravenous Eptifibatide and intracoronary Retaplastase in thrombus aspiration in patients undergoing Primary percutaneous coronary interventions (PPCI); Randomized clinical trial study)

#### Public title

effect of eptifibatide and reteplase on primary angioplasty outcomes

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Inclusion criteria: Ischemic typical chest pain extending more than 30 min; ST elevation 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:

Exclusion criteria: Rescue PCI after thrombolytic therapy; emergency CABG; AF; cardiogenic shock; TIMI flow grade 3 in primary angiography

#### Age

From **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

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Deputy of Research of Guilan University of Medical Sciences

##### Street address

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

##### City

Rasht

##### Postal code

#### 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

All patients will receive Emergency PCI treatment. Patients will receive 300 mg of chewing aspirin and 600 mg of Clopidogrel maintenance dose prior to the procedure before transferring to the catheterism room. In the first group, the patients undergo thrombus suction after the wiring, and then the stent is embedded. In the second group, the patients undergo thrombus suction after wiring, then receive 180µg / kg intra coronary bolus eptifibatide. Intra coronary eptifibatide will be injected 2 times with 10 minutes interval and then the stent will be embedded. In the third group, patients undergo thrombus suction after wiring, and then 6 mg intracoronary reteplase is injected and the stent will be embedded. In the fourth group, the patients undergo thrombus suction after wiring, then receive 180µg / kg intravenous bolus eptifibatide during 18 hours in the ward. After the procedure angiography report for TIMI

blush grade and corrected TIMI frame count will be seen. All patients will be treated with a maintenance dose of 75 mg clopidogrel daily for one year and 300 mg of aspirin for 30 days and then 100 mg.

**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**

Rasht- 15 khordad street- Next to Gilan Province Management and Planning Organization

**City**

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Deputy of Research of Guilan University of Medical Sciences

**Full name of responsible person**

dr. shadman nemati

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**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Deputy of Research of 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**

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**Position**

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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*