

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Study of the effect of early bolus dose of tirofiban in emergency department on early TIMI flow 3 of the patients with myocardial infarction undergoing primary PCI

Protocol summary

Study aim

The aim of this study is to consider the effect of early bolus administration of tirofiban in emergency department on early TIMI flow of the patients with myocardial infarction undergoing primary PCI.

Design

Two arm parallel group randomised trial with blinded postoperative care and outcome assessment

Settings and conduct

Tehran heart center

Participants/Inclusion and exclusion criteria

Inclusion criteria are the patients admitted in Tehran heart center emergency department with acute ST elevation myocardial infarction or new left bundle branch block within 12 hours of onset of symptoms and are candidate for primary PCI within 90 minutes of presentations to the emergency department. Exclusion criteria are contraindications for fibrinolysis, severe hepatic or renal failure, age more than 75 years old and fibrinolytic therapy within 24 hours from randomization. The sample size is 70 for each group.

Intervention groups

The sample size is 70 for each group. The patients are randomized into the following 2 groups. Intervention group are prescribed 25 mcg/kg of bolus intravenous tirofiban in 1-3 minutes as soon as possible in the emergency department. The control group will not receive tirofiban.

Main outcome variables

Early TIMI flow of the patients with myocardial infarction undergoing primary PCI.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT201105126463N1**

Registration date: **2011-06-06, 1390/03/16**

Registration timing: **registered_while_recruiting**

Last update: **2018-04-04, 1397/01/15**

Update count: **1**

Registration date

2011-06-06, 1390/03/16

Registrant information

Name

Mehdi Mousavi

Name of organization / entity

Alborz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 26 3457 0030

Email address

mmoosavi@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran Heart Center

Expected recruitment start date

2011-03-06, 1389/12/15

Expected recruitment end date

2012-03-05, 1390/12/15

Actual recruitment start date

2011-03-06, 1389/12/15

Actual recruitment end date

2012-03-19, 1390/12/29

Trial completion date

empty

Scientific title

Study of the effect of early bolus dose of tirofiban in

emergency department on early TIMI flow 3 of the patients with myocardial infarction undergoing primary PCI

Public title

Effect of early tirofiban administration in emergency department on TIMI flow 3

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Inclusion criteria: Acute myocardial infarction patient with ST segment elevation or new left bundle branch block in 12 hours of onset of symptoms and are candidate for primary PCI within 90 minutes of presentations to the emergency department

Exclusion criteria:

Exclusion criteria: Stroke or TIA within the past 30 days or any history of hemorrhagic stroke, well known intra cranial disease (neoplasm or aneurysm), any active bleeding or bleeding history in past 30 days, uncontrolled HTN at registry time (SBP>180, DBP>110), Major operation or trauma in recent 6 weeks, platelet count less than 100000 or bleeding conditions, Coagulation disorders (INR>1.5), Severe hepatic failure, Administration of any fibrinolytic treatment 24 hours from randomization, Renal failure (Cr>205mg/dl or GFR <30), age more than 75 years old

Age

To **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **140**

Actual sample size reached: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization

Blinding (investigator's opinion)

Double blinded

Blinding description

Participant Outcome assessor Data analyser Data and Safety Monitoring Board Are blinded by coding to the subjects

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran Heart Center Ethic committee

Street address

Jalal Al Ahmad & North Kargar cross

City

Tehran

Province

Tehran

Postal code

1411713138

Approval date

2011-01-03, 1389/10/13

Ethics committee reference number

460

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

Prevalence of TIMI 3 flow score in coronary angiography

Timepoint

in cath lab before PCI

Method of measurement

according to angiography report

Secondary outcomes

1

Description

Major Cardiac Event

Timepoint

one year

Method of measurement

clinical follow up

Intervention groups

1

Description

Intervention group are prescribed 25 mcg/kg of bolus intravenous tirofiban in 1-3 minutes as soon as possible in the emergency department.

Category

Treatment - Drugs

2**Description**

The control group will not receive tirofiban in emergency department.

Category

Treatment - Drugs

Recruitment centers1**Recruitment center****Name of recruitment center**

Tehran Heart Center

Full name of responsible person

Dr Mehdi Moosavi

Street address

Jalal Al Ahmad & North Kargar Cross

City

Tehran

Province

Tehran

Postal code

1411713138

Phone

+98 21 8802 9721

Email

mmoosavi@razi.tums.ac.ir

Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Dr Seyed Hesammeddin Abbasi

Street address

North kargar and Jalal al Ahmad cross

City

Tehran

Province

Tehran

Postal code

1411713138

Email

mmoosavi@razi.tums.ac.ir

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

Yes

Title of funding source

Tehran 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**

Tehran Heart Center

Full name of responsible person

Dr Seyed Hesammeddin Abbasi

Position

Managing editor of Journal of Tehran Heart Center

Latest degree

Ph.D.

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

Jalal Al Ahmad & North Kargar cross

City

Tehran

Province

Tehran

Postal code

1411713138

Phone

+98 21 8802 9702

Fax

+98 21 8802 9256

Email

Abbasi.hesam@gmail.com

Web page address

http://thc.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tehran Heart Center

Full name of responsible person

Dr Mehdi Mousavi

Position

Cardiologist, Fellow of interventional cardiology

Latest degree

Specialist

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

Jalal Al Ahmad & North Kargar cross

City

Tehran

Province

Alborz

Postal code

1411713138

Phone

+98 21 8802 9600

Fax

+98 21 8802 9256

Email

mmoosavi@razi.tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Mehdi Mousavi

Position

Fellowsip

Latest degree

Specialist

Other areas of specialty/work

Cardiology

Street address

Jalal Al Ahmad & North Kargar cross

City

Tehran

Province

Tehran

Postal code

1411713138

Phone

+98 21 8802 9600

Fax

+98 21 8802 9256

Email

mmoosavi@razi.tums.ac.ir

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The article

When the data will become available and for how long

Mar 2018

To whom data/document is available

Anyone

Under which criteria data/document could be used

No other documents

From where data/document is obtainable

The corresponding author

What processes are involved for a request to access data/document

Email to coresponding author

Comments