

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Evaluating the role of intravenous Pentoxifylline administration on increasing primary percutaneous coronary intervention (PPCI) success in ST elevation myocardial infarction (STEMI) patient

Protocol summary

Study aim

Investigating the role of pentoxifylline on success of primary PCI in patients with STEMI

Design

Two arm parallel group randomised trial with blinded postoperative care and outcome assessment that 320 patients diagnosed with Acute STEMI to perform Primary PCI are introduced to the Department of Cardiology, in the Heart Center of Tehran, who have criteria for entry will be included in the study. Patients, are divided to the two groups of 160 A and B, based on Permuted Block Randomization randomly.

Settings and conduct

This is a selective interventional study in which 320 patients diagnosed with Acute STEMI to perform Primary PCI are introduced to the Department of Cardiology, Tehran University of Medical Sciences, which, if they have criteria for entering the study, are selected and entered Will be studied

Participants/Inclusion and exclusion criteria

Entry requirements (Inclusion Criteria): patient older than 18 years of age who becomes a Primary PCI candidate: chest pain for less than or equal to 12 hours; Obtain consent from the patient; Exclusion Criteria: Patients unwilling to participate; Age less than 18; Start angina more than 12 hours; CPR before transition to cath-lab; Patients with history of cardiac transplantation; Patients with history of PCI or CABG in last month; Patients who received thrombolytic; Current use of pentoxifylline; Use of ketorolac in last 24 hours

Intervention groups

Patients are categorized randomly according to defined criteria in two groups of 160 patients. In one group, 50 mg IV bolus, then 50 mg in 30 minutes infusion of pentoxifylline, in addition to other routine treatments will be given. In the other group, placebo is given. Then, effects of pentoxifylline on coronary flow and myocardial

perfusion in the two groups will be investigated.

Main outcome variables

Coronary Flow Rate; Myocardial perfusion rate;

General information

Reason for update

Acronym

PENTOS

IRCT registration information

IRCT registration number: **IRCT20120111008698N24**

Registration date: **2019-08-02, 1398/05/11**

Registration timing: **registered_while_recruiting**

Last update: **2019-08-02, 1398/05/11**

Update count: **0**

Registration date

2019-08-02, 1398/05/11

Registrant information

Name

Azita Hajhossein Talasaz

Name of organization / entity

Department of Clinical Pharmacy, Faculty of Pharmacy, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 66954709

Email address

atalasaz@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-20, 1398/03/30

Expected recruitment end date

2020-01-20, 1398/10/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluating the role of intravenous Pentoxifylline administration on increasing primary percutaneous coronary intervention (PPCI) success in ST elevation myocardial infarction (STEMI) patient

Public title
Evaluating the role of intravenous pentoxifylline on successfullness of stenting in patients with myocardial infarction

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Patients older than 18 who are candidate for primary PCI. Pain or chest discomfort greater than or equal to 20 minutes, less than or equal to 12 hours, and ST elevation ≥ 1 mm in the adjacent limb leads and precordial leads except for V2, V3, or ST elevation ≥ 2 mm in V2, V3 in men or ST height ≥ 1.5 mm in V2, V3 in women. Obtain informed consent from all patients before enrollment.
Exclusion criteria:
Start angina more than 12 hours CPR before transition to cath-lab Patients with history of cardiac transplantation Patients with history of PCI or CABG in last month Patients who received thrombolytic Current use of pentoxyfilline Use of ketorolac in last 24 hours

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

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

Sample size
Target sample size: **320**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, Permuted Block randomization method was used individually. The randomized list of numbers 1 to 320 is randomly divided into two groups A or B, and the admitted patients are listed in group A or B, respectively.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, researchers and data analysers are unaware of the allocation of study groups, and those who prepare a draft article are also kept blind to the

allocation of blind study groups Patients in group A or B and receiving a drug or placebo by the patient are unaware.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
Tehran University of Medical Sciences
City
Tehran
Province
Tehran
Postal code
1417653761

Approval date
2018-03-10, 1396/12/19

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1396.4760

Health conditions studied

1

Description of health condition studied
Acute myocardial infarction

ICD-10 code
I21

ICD-10 code description
ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction

Primary outcomes

1

Description
coronary blood flow and myocardial perfusion

Timepoint
during angiography

Method of measurement
TIMI flow criteria and observations during the angiography

Secondary outcomes

1

Description

hs-CRP

Timepoint

baseline and 48 hours after PCI

Method of measurement

blood sample

2

Description

TNT

Timepoint

baseline and 24 hours and 48 hours after PCI

Method of measurement

blood sample

3

Description

30 day MACE

Timepoint

one month after PCI

Method of measurement

follow-up visit or phone call

4

Description

TFC

Timepoint

during angiography

Method of measurement

TIMI frame count and observations during the angiography

5

Description

MBG

Timepoint

during angiography

Method of measurement

myocardial blush grade and observations during the angiography

Intervention groups

1

Description

Intervention group: Administration of intravenous pentoxifylline; 50 mg IV bolus, then 50 mg IV infusion in 30 minutes

Category

Treatment - Drugs

2

Description

Control group: Administration of solvent: NaCl 0.9 % serum

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Heart Center

Full name of responsible person

Azita Hajhossein Talasaz

Street address

Tehran Heart Center

City

Tehran

Province

Tehran

Postal code

88029731

Phone

+98 21 8802 9261

Email

atalasaz@razi.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Ali Sahraian

Street address

Department of Environmental Health Engineering,
School of Public Health, Tehran University of Medical
Sciences

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 8163 3686

Email

atalasaz@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 University of Medical Sciences

Full name of responsible person

Dr. Hessam Kakavand

Position

Pharmacotherapy resident

Latest degree

Master

Other areas of specialty/work

Medical Pharmacy

Street address

Pharmacotherapy Department, Faculty of Pharmacy,
Tehran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

88029731

Phone

+98 21 8802 9261

Email

hessamkakavand@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Azita Hajhossein Talasaz

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Medical Pharmacy

Street address

Pharmacotherapy Department, Faculty of Pharmacy,
Tehran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

88029731

Phone

+98 21 2260 6951

Email

atalasaz@razi.tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Hessam Kakavand

Position

Pharmacotherapy resident

Latest degree

Master

Other areas of specialty/work

Medical Pharmacy

Street address

Pharmacotherapy Department, Faculty of Pharmacy,
Tehran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

88029731

Phone

+98 21 2260 6951

Email

hessamkakavand@yahoo.com

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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Data such as primary and secondary outcome information

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

For researchers working in academic and scientific institutions

Under which criteria data/document could be used

Conditions for using the data or documentation will be determined depending on the type of use, with the coordinator of the project

From where data/document is obtainable

E-mail: a-talasaz@tums.ac.ir

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

E-mail: a-talasaz@tums.ac.ir

Comments