Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 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 pentoxyfilline; 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

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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
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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
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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
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

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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