

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Feb 2026

The efficacy of pentoxifylline in prevention of contrast-induced nephropathy in patients with myocardial infarction undergoing coronary angioplasty: A randomized clinical trial

Protocol summary

Summary

This single-blind prospective study aims to determine the efficacy of pentoxifylline in preventing contrast-induced nephropathy in patients with myocardial infarction undergoing coronary angioplasty. A total of 182 adult patients (age > 18 years) with ST elevation myocardial infarction (STEMI) referred to the Department of Cardiology, Imam Reza Hospital (Mashhad, Iran) for emergency angioplasty will be recruited. The exclusion criteria will be serum creatinine more than 1.5 mg/dl, heart failure, history of end-stage renal failure or being on dialysis, use of N-acetyl cysteine, theophylline, aminoglycosides, and nonsteroidal anti-inflammatory drugs, intravenous contrast media administration within the past two days, pulmonary edema, multiple myeloma, and uncontrolled hypertension. The patients will be randomly assigned to the case and control groups (n = 91 each) using block randomization. The control group will receive routine treatment (normal saline 1-1.5 cc/kg from 6 hours before to six hours after angioplasty) without pentoxifylline (PTX). The case group will receive routine treatment plus PTX (400 mg/tid from 24 h before to 24 h after coronary angioplasty). Serum creatinine will be measured before and 2 days after the procedure. Two groups will be compared according to the occurrence of contrast-induced nephropathy within 48 hours after the procedure.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014092819316N1**

Registration date: **2016-07-05, 1395/04/15**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-07-05, 1395/04/15

Registrant information

Name

Pouya Nezafati

Name of organization / entity

Mashhad University of Medical Sciences

Country

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nezafatip871@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Mashhad University of Medical Sciences

Expected recruitment start date

2013-10-20, 1392/07/28

Expected recruitment end date

2014-07-20, 1393/04/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of pentoxifylline in prevention of contrast-induced nephropathy in patients with myocardial infarction undergoing coronary angioplasty: A randomized clinical trial

Public title

Effect of pentoxifylline in preventing contrast-induced nephropathy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Consent to participate; ST elevation myocardial infarction (STEMI) and age over 18 years.

Exclusion criteria: serum creatinine more than 1.5 mg/dl, heart failure; history of end-stage renal failure or being on dialysis; use of N-acetyl cysteine, theophylline, aminoglycosides, and nonsteroidal anti-inflammatory drugs; intravenous contrast media administration within the past two days; pulmonary edema; multiple myeloma; and uncontrolled hypertension

Age

From **18 years** old to **85 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **182**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization was performed using block randomization method

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Mashhad University of Medical Sciences

City

Mashhad

Postal code

Approval date

2013-11-20, 1392/08/29

Ethics committee reference number

IRMUMSREC139283

Health conditions studied

1

Description of health condition studied

ST elevation myocardial infarction

ICD-10 code

I21

ICD-10 code description

Acute myocardial infarction

Primary outcomes

1

Description

Serum creatinine levels

Timepoint

Before angioplasty, two days after angioplasty

Method of measurement

Blood test

2

Description

Contrast-induced nephropathy

Timepoint

48 hours after angioplasty

Method of measurement

Blood test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Normal saline (1-1.5 cc/kg from 6 hours before to 6 hours after coronary angioplasty) plus pentoxifylline (400 mg/tid from 24 h before to 24 h after coronary angioplasty).

Category

Treatment - Drugs

2

Description

Control group: Normal saline (1-1.5 cc/kg from six hours before to six hours after coronary angioplasty)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Dr Ali Eshraghi

Street address

Imam Reza Sq., Ibn-e-Sina St.

City

Mashhad

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

Vice chancellor for research of Mashhad University of Medical Sciences

Full name of responsible person

Dr Ali Eslami

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Daneshgah Ave.

City

Mashhad

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

Yes

Title of funding source

Vice chancellor for research of Mashhad 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**

Mashhad University of Medical Sciences

Full name of responsible person

Dr Ali Eshraghi

Position

Cardiologist

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Web page address**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*