

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Randomized trial of pentoxifylline in pre-procedural cardiac injury following angioplasty in patients with ischemic heart diseases

Protocol summary

Summary

Objective: To evaluate the effect of pentoxifylline on cardiac pre-procedural injury in patients undergoing angioplasty. Design: A prospective, single blinded, randomized controlled trial on patients with ischemic heart diseases who undergoing angioplasty. Setting and conduct: All patients with ischemic heart diseases who undergoing angioplasty in Shahid Madani Hospital will be randomized (using permuted block randomization, block size 2, allocation ratio 1:1) in two groups of pentoxifylline treated (n=40) and control (n=40). Participants: All consented patients with ischemic heart diseases aged 18-80 who undergoing angioplasty and stent insertion. The exclusion criteria will include elevation of CK-MB and cTnI before PCI, history of CABG during last three months, history of previous MI, renal dysfunction (creatinine above 2.5 mg/dl), unsuccessful PCI, acute MI, cardiogenic shock, dialysis, pregnancy, inability in filling and understanding of the consent form, unconsented patients, patients who want to discontinue the study at any time. Intervention: In pentoxifylline group, all patients will be received totally 1200 mg oral pentoxifylline in three divided doses before PCI plus standard treatment. The control group will be received only standard treatment. Primary outcomes: Change of CK-MB and cTnI level before, 8, and 24 hours after PCI in each groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201402068307N4**

Registration date: **2014-03-10, 1392/12/19**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-03-10, 1392/12/19

Registrant information

Name

Taher Entezari-Maleki

Name of organization / entity

Tehran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences.

Expected recruitment start date

2013-12-12, 1392/09/21

Expected recruitment end date

2014-03-20, 1392/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Randomized trial of pentoxifylline in pre-procedural cardiac injury following angioplasty in patients with ischemic heart diseases

Public title

Evaluation of pentoxifylline in pre-procedural cardiac injury following angioplasty in patients with ischemic heart diseases

Purpose

Prevention

Inclusion/Exclusion criteria
Inclusion criteria: Ischemic heart diseases patients; age 18-80; undergoing of angioplasty with stent insertion; filling of consent form. Exclusion Criteria: Elevation of CK-MB and cTnI before PCI; history of CABG during last three months; history of previous MI; renal dysfunction (creatinine above 2.5 mg/dl); unsuccessful PCI; acute MI; cardiogenic shock; dialysis; pregnancy; inability in filling and understanding of the consent form; unconsented patients; patients who want to discontinue the study at any time.

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Randomization will be performed using permuted block randomization with a block size of 2 and an allocation ratio of 1:1 in two groups of Pentoxifylline and control.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Committee on Medical Ethics of Tabriz University of Medical Sciences

Street address
Golgasht Street

City
Tabriz

Postal code

Approval date
2013-12-02, 1392/09/11

Ethics committee reference number
92186

Health conditions studied

1

Description of health condition studied

Effect of pentoxifylline in pre-procedural cardiac injury following angioplasty in ischemic heart diseases patients

ICD-10 code

I20-I25

ICD-10 code description

Ischemic heart diseases

Primary outcomes

1

Description

CK-MB level

Timepoint

Before, 8 and 24 hours after angioplasty

Method of measurement

ELISA kits

2

Description

cTnI level

Timepoint

Before, 8 and 24 hours after angioplasty

Method of measurement

ELISA kits

Secondary outcomes

empty

Intervention groups

1

Description

Intervention: In pentoxifylline group, all patients will be received totally 1200 mg oral pentoxifylline in three divided doses before PCI plus the standard treatment.

Category

Treatment - Drugs

2

Description

Control: In the control group, patients only will be given the standard treatment.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Madani Heart Center of Tabriz

Full name of responsible person

Dr. Taher Entezari-Maleki

Street address

Shahid Madani Heart Center, Daneshghah Street

City

Tabriz

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

Vice chancellor for research, Tabriz University of Medical Sciences.

Full name of responsible person

Dr. Mohammad Reza Rashidi

Street address

Daneshghah street

City

Tabriz

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

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Taher Entezari-maleki

Position

Assistant professor/ Clinical pharmacist

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

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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