Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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Taher Entezari-Maleki
Name of organization / entity
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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

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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