Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of preventive effects of pentoxyfylline in contrast induced nephropathy in diabetic patients undergoing angioplasty

Protocol summary

Summary

To evaluate the effect of pentoxifylline on in diabetic patients undergoing angioplasty. Design: A prospective, not blinded blinded, randomized controlled trial on patients with ischemic heart diseases and diabetes who undergoing angioplasty. Setting and conduct: All patients with ischemic heart diseases and diabetes 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=45) and control (n=45). Participants: All consented patients with ischemic heart diseases and diabetes aged 18-85 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: mesurement of cystatin c before and 24 hours after PCI in each groups.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT201603038307N14**
Registration date: **2017-07-09, 1396/04/18**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-07-09, 1396/04/18

Registrant information

Name

Taher Entezari-Maleki

Name of organization / entity

Tehran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences.

Expected recruitment start date

2016-06-05, 1395/03/16

Expected recruitment end date

2017-01-10, 1395/10/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of preventive effects of pentoxyfylline in contrast induced nephropathy in diabetic patients undergoing angioplasty

Public title

Evaluation of preventive effects of pentoxyfylline in contrast induced nephropathy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Ischemic heart diseases and diabetic patients; age 18-85; 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 **85 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

-

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

ethic commite of tabriz university of medical science

Street address

golgasht

City

tabriz

Postal code

-

Approval date

2016-01-04, 1394/10/14

Ethics committee reference number

tbzmed.rec.1395.4

Health conditions studied

1

Description of health condition studied

diabetes mellitus undergoing angioplasty

ICD-10 code

E11 and I2

ICD-10 code description

diabetes mellitus and ischemic heart disease

Primary outcomes

1

Description

cystatin c

Timepoint

24 hours before and after

Method of measurement

elisa kit

Secondary outcomes

1

Description

creatinine

Timepoint

24 hours before angioplasty and after

Method of measurement

elisa kit

Intervention groups

1

Description

intervention group will recieve 1200 mg pentoxyfylline three times divided dose with standard treatments control group will only recieve standard treatments

Category

Treatment - Drugs

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

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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
daneshgah street
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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

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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