Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

¬¬A randomized double blind placebo controlled trial examining the effects of Pentoxifylline on Contrast Induced Nephropathy reduction after percutaneous coronary intervention in high risk candidates

Protocol summary

Summary

Background: Contrast-induced nephropathy (CIN) (known as contrast-induced acute kidney injury) occurs as a result of acute worsening of renal function following a procedure with administration of iodine contrasts agent and remains a substantial concern in clinical practices. The purpose of this study is to investigate the preventive effect of Pentoxifylline supplementation on reduction of CIN occurrence after percutaneous coronary intervention among patients who were high risk of CIN according to Mehran score. Methods: In randomized, double-blind clinical trial patients who undergo coronary angiography with Mehran Score ≥ 11 consisted of our population. Patients in a ratio 1:1, divided into two groups received saline 0.9% plus N-acetyl cysteine and Pentoxifylline 400 mg three times per day 24 hours before angiography until 48 hours after angiography. In control group, patients received placebo instead of PTX in a same manner as the control group. The endpoint was the incidence of CIN defined as creatinine increase of 0.5 mg/dL within 2 days after contrast. Results: There were no significant differences in baseline characteristics. CIN occurred in 3(5.5%) and 4(7.3%) patients of the both groups (Pentoxifylline and control), respectively (p=0.69; incidence odds ratio 1.36; 95% CI 0.29-6.38). No significant differences were seen in secondary outcome measures and changes in the level of creatinine (p=0.54). Conclusion: In high-risk patients undergoing coronary angiography pentoxifylline supplementation had protection effect against contrast-induced nephropathy greater than placebo based hydration, but, not supported by our data.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016111530905N1**
Registration date: **2017-03-01, 1395/12/11**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-03-01, 1395/12/11

Registrant information

Name

Farnaz Barzi

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Imam Hossien Hospital

Expected recruitment start date

2014-01-01, 1392/10/11

Expected recruitment end date

2014-08-27, 1393/06/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

¬¬A randomized double blind placebo controlled trial

examining the effects of Pentoxifylline on Contrast Induced Nephropathy reduction after percutaneous coronary intervention in high risk candidates

Public title
PTX and Contrast Induced Nephropathy
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criterion was only Mehran score more than or equal to 11. Exclusion criteria included need for urgent coronary angiography in the first 48 hours after admission, history of contrast media usage in previous 14 days or renal failure in recent six months, multiple myeloma, pregnancy or breastfeeding and pre-planned use of any other measure for CIN prevention apart from PTX consumption.
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **110**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical Committee of the ShahidBeheshtiUniversity of Medical Sciences
Street address
ShahidBeheshtiUniversity of Medical Sciences
City
Tehran
Postal code
Approval date
2012-11-11, 1391/08/21
Ethics committee reference number
1250

Health conditions studied

1

Description of health condition studied
patients candidate for percutaneous coronary intervention
ICD-10 code
N14.1
ICD-10 code description
نفروپاتی القا شده بوسیله سایر داروها، مواد بیولوژی و دارویی

Primary outcomes

1

Description
Contrast Induced Nephropathy
Timepoint
once
Method of measurement
48 hours after angiography

Secondary outcomes

1

Description
Cratinine
Timepoint
before and 48 hours after the intervention
Method of measurement
Laboratory unit

Intervention groups

1

Description
placebo capsules plus N-acetyl cysteine
Category
Treatment - Drugs

2

Description
Pentoxifylline plus N-acetyl cysteine
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hossien hospital
Full name of responsible person
Dr.Farnaz Barzi
Street address
City

Tehran

2

Recruitment center
Name of recruitment center
Imam Hossein Hospital
Full name of responsible person
Dr.Farnaz Barzi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Imam Hossein Hospital
Full name of responsible person
Imam Hossein Hospital
Street address
Shahid Madani st
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Imam Hossein Hospital
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
School of Medicine, ShahidBeheshti University of Medical Sciences
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Person responsible for updating data

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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