

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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 contrast 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

نفریاتی 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

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Web page address

2

Recruitment center

Name of recruitment center

Imam Hossein Hospital

Full name of responsible person

Dr.Farnaz Barzi

Street address

City

Tehran

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

Full name of responsible person

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Position

Assistant Professor in Nephrology

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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