

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluating the Protective Effect of Pentoxifylline on Contrast Induced Nephropathy

Protocol summary

Summary

Introduction: Contrast induced nephropathy (CIN) is a pathologic process in the kidney that may happen after exposure to iodinated media. CIN is clinically defined as a rise in serum creatinine of greater than 25% or more than 0.5 mg/dl within a period of 72 hours of receiving intravenous contrast. Percutaneous coronary intervention provides a high risk condition for incidence of CIN even in patients with normal renal function. Pentoxifylline (PTX) with a variety of mechanisms may prevent CIN. Materials and methods: Between April 5th, 2011 and February 20th, 2012, all consecutive eligible patients referred for elective percutaneous coronary intervention were asked to take part in the study. Eligibility was defined as the age between 18 and 65 years and baseline serum creatinine ≤ 1.5 mg/dl. The patients were randomly allocated to two groups either receiving saline or saline plus pentoxifylline 400 mg orally three times a day for 48 hours. Serum creatinine, was measured 24 hours prior to the procedure and 48 hours thereafter. The primary endpoint was occurrence of CIN defined as 25% rise in serum creatinine 48 hours after the procedure.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201011135161N1**

Registration date: **2012-07-25, 1391/05/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-07-25, 1391/05/04

Registrant information

Name

Vahideh Yavari

Name of organization / entity

Shiraz University of Medical Sciences, Shiraz, Iran

Country

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Recruitment status

Recruitment complete

Funding source

Vice-Chancellery of Research and Technology, Shiraz University of Medical Sciences, Shiraz, Iran

Expected recruitment start date

2011-04-05, 1390/01/16

Expected recruitment end date

2012-02-20, 1390/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the Protective Effect of Pentoxifylline on Contrast Induced Nephropathy

Public title

Pentoxifylline and Contrast Induced Nephropathy

Purpose

Prevention

Inclusion/Exclusion criteria

Eligibility was defined as the age between 18 and 65 years and baseline serum creatinine ≤ 1.5 mg/dl.

Exclusion criteria were acute myocardial infarction, congestive heart failure, hemodynamic instability during or after procedure, known allergy or previous

administration of pentoxifylline and use of concomitant nephrotoxic agents and diuretics.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **199**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Committee of Ethics in Medical Researches, Shiraz
University of Medical Sciences

Street address

Shiraz University of Medical Sciences, Research
Affairs Management Office

City

Shiraz

Postal code

Approval date

2011-10-06, 1390/07/14

Ethics committee reference number

ct-90-2507

Health conditions studied

1

Description of health condition studied

Contrast Induced Nephropathy

ICD-10 code

N 17

ICD-10 code description

Acute renal failure (includes acute renal impairment)

Primary outcomes

1

Description

Serum creatinine

Timepoint

24 hours before intervention and 48 hours after PCI

Method of measurement

Blood test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention arm: Pentoxifylline (Trental) 400 mg PO
three times a day for 24 hours before and 24 hours after
PCI+1 ml/kg/h of 0.9 saline for 6 hours prior to and 6
hours after the procedure

Category

Prevention

2

Description

Control arm: 1 ml/kg/h of 0.9 saline for 6 hours prior to
and 6 hours after PCI

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Kowsar hospital

Full name of responsible person

Dr. Mohammad Ali Ostovan

Street address

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research Affairs, Shiraz University
of Medical Sciences

Full name of responsible person

Dr.Gholam Reza Hatam

Street address

Vice-chancellor for Research Affairs, Shiraz University
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City

Shiraz

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 Affairs, Shiraz 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****Name of organization / entity**

Shiraz Nephro-urology Research Center, Shiraz University of Medical Sciences, Shiraz, Iran

Full name of responsible person

Jamshid Roozbeh

Position

Professor of Nephrology

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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