

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 2026

### Evaluation of the effect of oral pentoxifylline on prevention of radiocontrast nephropathy in patient that undergone angiography

#### Protocol summary

##### Study aim

A comparison of the effect of pentoxifylline on the prevention of radio contrast nephropathy in patients with renal dysfunction and patients with normal renal function

##### Design

Patients are divided into two groups: normal kidney function and renal dysfunction, and each group is randomly divided into two groups to receive saline or saline with pentoxifylline (400 mg orally three times a day). Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 190 patients. Use the rand function of Excel software to randomize Sampling will be continuous. The statistical method used is SPSS software

##### Settings and conduct

Each group of patients will be divided into two groups of normal saline 1cc / kg / h and normal saline and pentoxifylline (400 mg orally three times a day). Patients' creatinine will be tested the day before angiography the next day and 48 hours later, and at the end the two groups will be compared and the CKD patients in the groups will be compared. Patients, statistical analyzers, and researchers will be blind.

##### Participants/Inclusion and exclusion criteria

Criteria for entering the study of all patients who need to perform vascular angiography in terms of cardiac service. Criteria for exclusion of the study are patients with stage 5 CKD , kidney transplantation, patients with renal insufficiency with a GFR below 30, and patients with a history of allergy to pentoxifylline according to history.

##### Intervention groups

Get normal saline serum with pentoxifylline (400 mg orally three times a day for 24 hours before angiography(1st group), get normal saline for 2nd group

##### Main outcome variables

Creatinine and its clearance are the main variables. Other variables are urinary output, protein excretion, CRP, urine examination.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20161219031464N4**

Registration date: **2020-09-08, 1399/06/18**

Registration timing: **retrospective**

Last update: **2020-09-08, 1399/06/18**

Update count: **0**

##### Registration date

2020-09-08, 1399/06/18

##### Registrant information

##### Name

fatemeh yassari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2712 1000

##### Email address

fatameh.yassari@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-02-20, 1398/12/01

##### Expected recruitment end date

2020-05-21, 1399/03/01

##### Actual recruitment start date

2020-02-20, 1398/12/01

##### Actual recruitment end date

2020-06-14, 1399/03/25

##### Trial completion date

2020-07-10, 1399/04/20

##### Scientific title

Evaluation of the effect of oral pentoxifylline on prevention of radiocontrast nephropathy in patient that undergone angiography

#### Public title

Investigation of the effect of pentoxifylline on the prevention of radio contrast nephropathy

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

The criteria for entering the study include patients who are candidates for angiography with cardiac service indications and will be admitted to cardiac service.

##### Exclusion criteria:

patients with stage 5 CKD, kidney transplantation, patients with renal insufficiency with a GFR below 30 patients with a history of allergy to pentoxifylline according to history.

#### Age

From **18 years** old to **75 years** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

#### Sample size

Target sample size: **192**

Actual sample size reached: **190**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

This division is based on a table of random numbers. The method of randomization is simple. According to the table of numbers, patients are divided into two groups: case and control. Patients who visit on even days will be in the target group and patients who are admitted on odd days will be in the control group

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

In this study, participants and who evaluated the results and analyzer of the data were blind. Patients who are candidates for angiography are coded according to the schedule. The person encoding is blind about the target and control group. The patient then enters the group based on the received code. Data collection and analysis is done by someone who has no knowledge of the details.

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

#### Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Shahid Beheshti Medical University

##### Street address

Masih Daneshvari Hospital, Darabad Avenue, Shahid Bahonar roundabout, Tehran, Iran

##### City

Tehran

##### Province

Tehran

##### Postal code

1956944413

#### Approval date

2020-01-22, 1398/11/02

#### Ethics committee reference number

IR.SBMU.NRITLD.REC.1399.039

## Health conditions studied

### 1

#### Description of health condition studied

Kidney disorders caused by contrast material following angiography

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Serum creatinine and creatinine clearance

#### Timepoint

Serum creatinine and clearance creatinine of patients will be tested the day before and the next day and 48 hours later

#### Method of measurement

blood and urine sample examination

### 2

#### Description

C reactive protein

#### Timepoint

The day before and after angiography

#### Method of measurement

Blood test

### 3

#### Description

Proteinuria

#### Timepoint

The day before and after angiography

#### Method of measurement

Urine examination

## Secondary outcomes

empty

## Intervention groups

1

### Description

Intervention group: In this group, they receive normal saline at a dose of one cc per kilogram of body weight and pentoxifylline (400 mg orally every 8 hours) for 12 hours before and 12 hours after angiography,

### Category

Prevention

2

### Description

Control group: In this group, patients will receive 1 cc of normal serum saline per kilogram of body weight from 12 hours before to 12 hours after angiography.

### Category

Diagnosis

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Masih Daneshvari Hospital

#### Full name of responsible person

Fatemeh Yassari

#### Street address

Masih Daneshvari Hospital, Darabad Avenue, Shahid Bahonar roundabout, Tehran, Iran

#### City

Tehran

#### Province

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#### Postal code

1956944413

#### Phone

+98 21 2712 3000

#### Email

fa.yassari@gmail.com

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Shahid Beheshti University of Medical Sciences

#### Full name of responsible person

Afshin Zarghi

#### Street address

Masih Daneshvari Hospital, Shahid Bahonar St. (Niavaran), Darabad,

#### City

Tehran

### Province

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### Postal code

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### Phone

+98 21 2712 1000

### Email

fa.yassari@gmail.com

### Grant name

### Grant code / Reference number

### Is the source of funding the same sponsor organization/entity?

Yes

### Title of funding source

Shahid Beheshti University of Medical Sciences

### Proportion provided by this source

100

### Public or private sector

Public

### Domestic or foreign origin

Domestic

### Category of foreign source of funding

empty

### Country of origin

### Type of organization providing the funding

Academic

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Shahid Beheshti University of Medical Sciences

#### Full name of responsible person

Fatemeh Yassari

#### Position

Assistant professor

#### Latest degree

Subspecialist

#### Other areas of specialty/work

Internal Medicine

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## Person responsible for scientific inquiries

### Contact

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Shahid Beheshti University of Medical Sciences

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**Position**

Assistant professor

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable