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 angiographye

Protocol summary

Study aim

A comparison of the effect of pentoxifylline on the prevention ofradio 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 foe 2nd group

Main outcome variables

Creatinine and it"s 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

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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 angiographye

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
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Masih Daneshvari Hospital, Darabad Avenue, Shahid Bahonar roundabout, Tehran, Iran
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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,
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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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Position
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Latest degree
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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