

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 2026

### Effectiveness of oral pentoxifylline for the prevention of contrast nephropathy in CKD patients undergoing coronary angiography

#### Protocol summary

##### Summary

(1) Determine the average levels of blood creatinine in the group receiving the NAC; To determine the effect of changes in serum creatinine in the group receiving pentoxifylline plus NAC; Determine and compare the prevalence of blood creatinine changes in the group receiving the NAC plus pentoxifylline with NAC alone; The frequency of contrast-induced nephropathy in patients undergoing coronary angiography (2) Controlled clinical trial (3) Measurement of serum creatinine level before angiography. Patients were randomly divided into two equal groups (4) The terms of inclusion: ckd with angiography and cardiac catheterization; Age greater than 18 and less than 75 years; Terms of withdrawal from the study follow-up treatment with theophylline in the previous month, furosemide, mannitol or dopamine, nonsteroidal anti-inflammatory drugs, renal failure; Patients with serum creatinine equal to or less than 1.5 mg per deciliter; Sensitivity to contrast material, emergency coronary angiography; Radiocontrast diagnostic use in the last 2 months for reasons other diagnostic; Congestive heart failure (5) The administration of NAC 1200 mg every 12 hours in addition to hydration the day before angiography and prescribed pentoxifylline 400 mg every 8 hours in addition to hydration and N-acetylcysteine. Measure and record patients' serum creatinine levels in both groups after 24 hours and compared with admission creatinine. (6) Serum creatinine

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015102624713N1**

Registration date: **2016-03-09, 1394/12/19**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-03-09, 1394/12/19

##### Registrant information

###### Name

Mahmood Kordi

###### Name of organization / entity

Zahedan University of Medical Science

###### Country

Iran (Islamic Republic of)

###### Phone

+98 54 3328 7533

###### Email address

mkordi@zaums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research,Zahedan University of Medical Sciences

##### Expected recruitment start date

2016-01-09, 1394/10/19

##### Expected recruitment end date

2016-11-21, 1395/09/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effectiveness of oral pentoxifylline for the prevention of contrast nephropathy in CKD patients undergoing coronary angiography

##### Public title

Effectiveness of pentoxifylline in contrast induced nephropathy

## Purpose

Prevention

## Inclusion/Exclusion criteria

Inclusion criteria of ckd patients with angiography and cardiac catheterization indication include:Age greater than 18 and less than 75 years, Patient satisfaction for the study Exclusion criteria include : problems in patients follow up, treatment with theophylline, furosemide, mannitol or dopamine in last one month, use of Nonsteroidal anti-inflammatory drugs, aminoglycosides, N-acetylcysteine drugs, Renal failure patients with serum creatinine equal to or less than 1.5 mg per deciliter, Patients with an allergy to contrast material, Patients with Multiple myeloma, Pulmonary edema, Uncontrolled hypertension, patient required emergency angiography, diagnostic use of radiocontrast material for patient in the last 2 months of other diagnostic reasons, congestive heart failure, pregnancy, lactation Sensitivity to the NAC or pentoxifylline

## Age

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

## Gender

Both

## Phase

2

## Groups that have been masked

*No information*

## Sample size

Target sample size: **60**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Zahedan Medical University of Science

##### Street address

Ethics Committee of Zahedan Medical University of Science, Zahedan Medical University of Science, Dr.Hesabi Square, Daneshgah Avenue, Zahedan

##### City

Zahedan

##### Postal code

#### Approval date

2015-09-23, 1394/07/01

## Ethics committee reference number

IR.ZAUMS.REC.1394.221

## Health conditions studied

### 1

#### Description of health condition studied

Contrast Nephropathy

#### ICD-10 code

N17, N18,

#### ICD-10 code description

Renal failure

## Primary outcomes

### 1

#### Description

Serum Creatine

#### Timepoint

at admission, 24 h after intervention

#### Method of measurement

blood test based on milligram on decilitre

## Secondary outcomes

### 1

#### Description

Contrast Nephropathy

#### Timepoint

24 hours

#### Method of measurement

blood test based on milligram on decilitre

## Intervention groups

### 1

#### Description

In the control group N-acetylcysteine 1200 mg administered every 12 hours in addition to hydration will be prescribed

#### Category

Treatment - Drugs

### 2

#### Description

In the intervention group, prescribed pentoxifylline 400 mg every 8 hours plus hydration and NAC In the control group , prescription N-acetylcysteine 1200 mg every 12 hours is recommended in addition to hydration

#### Category

Treatment - Drugs

## Recruitment centers

1

**Recruitment center**

**Name of recruitment center**

Ali Ebn Abi Taleb Hospital, Zahedan

**Full name of responsible person**

Mahmoud kordi

**Street address**

Internal Medicine Department, Zahedan Ali ibn Abi Talib Hospital, Salamat Blvd, Dr.Hesabi Sq., Zahedan

**City**

Zahedan

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Vice chancellor for research,Zahedan University of Medical Sciences

**Full name of responsible person**

Mohsen Taheri

**Street address**

, Vice chancellor for research, Zahedan University of Medical Sciences, Hesabi Square, Zahedan

**City**

Zahedan

**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,Zahedan 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**

Zahedan Medical University

**Full name of responsible person**

Mahmoud Kordi

**Position**

Internal medicine residence

**Other areas of specialty/work**

**Street address**

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**Full name of responsible person**

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**Position**

Internal Medicine Specialist, Nephrologist

**Other areas of specialty/work**

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**Position**

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**Other areas of specialty/work**

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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*