

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### Effect of allopurinol in preventing contrast induced nephropathy among patients undergoing elective PCI

#### Protocol summary

##### Summary

The aim of this study is to evaluate the efficacy of allopurinol in preventing contrast induced nephropathy. Inclusion criteria is admission for elective PCI and exclusion criteria is serum creatinin > 3mg/dL or eGFR < 60ml/min; sever hepatic failure; concomitant use of 6mercaptapurin or azathioprine or warfarin. The study population is all patients admitted for elective PCI in Tehran Heart Center and the sample size is 200. 24 hours before PCI, blood samples are drawn to measure serum creatinin, uric acid, and serum cystatin C. After that patients are grouped in two groups-placebo and intervention. Patients in the intervention group receive two doses of 600mg allopurinol, one 24 hours and one immediately before the procedure. The control group will receive the placebo at these times. 24 hours after the procedure, another blood sample will be drawn to measure serum creatinin, uric acid, and serum cystatin C. The rate of contrast induced nephropathy will be compared between the two groups using aforementioned biomarkers. Also, adverse drug reactions will be recorded.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015120525372N1**

Registration date: **2017-06-06, 1396/03/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-06-06, 1396/03/16

##### Registrant information

###### Name

Zahra Alimohammad Ghelichkhan

###### Name of organization / entity

Urmia University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8840 0871

###### Email address

z-ghelichkhan@razi.tums.ac.ir

###### Recruitment status

**Recruitment complete**

###### Funding source

Tehran University of Medical Sciences

###### Expected recruitment start date

2012-10-13, 1391/07/22

###### Expected recruitment end date

2014-09-01, 1393/06/10

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

Effect of allopurinol in preventing contrast induced nephropathy among patients undergoing elective PCI

###### Public title

Effect of allopurinol in preventing kidney damage due to coronary angiography

###### Purpose

Prevention

###### Inclusion/Exclusion criteria

Inclusion criteria: All patients undergoing elective PCI

Exclusion criteria: Patients who are candidates for CABG or primary PCI; Patients with gout or prior use of allopurinol; Serum creatinin > 3mg/dL or eGFR < 60ml/min; Advanced hepatic failure; Patients who are using azathioprine, 6MP, or warfarin; Patients who

have not filled/signed consent form, or the ones who had shown adverse reaction to the drug in prior use

#### Age

From **18 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **200**

#### 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

Ethics committee of Tehran University of Medical Sciences

###### Street address

Tehran University of Medical Sciences

###### City

Tehran

###### Postal code

##### Approval date

2015-05-23, 1394/03/02

##### Ethics committee reference number

149384-28024-159-01-94

### Health conditions studied

#### 1

##### Description of health condition studied

contrast induced nephropathy

##### ICD-10 code

Y57.5

##### ICD-10 code description

X-ray contrast media

### Primary outcomes

#### 1

##### Description

serum cystatin C

##### Timepoint

24 hours after PCI

##### Method of measurement

blood sample

#### 2

##### Description

serum creatinin

##### Timepoint

24 hours after PCI

##### Method of measurement

blood sample

### Secondary outcomes

#### 1

##### Description

serum uric acid

##### Timepoint

24 hours before and after PCI

##### Method of measurement

blood sample

### Intervention groups

#### 1

##### Description

allopurinol, 600 mg PO, 24 hours before PCI

##### Category

Treatment - Drugs

#### 2

##### Description

placebo, 24 hours before PCI

##### Category

Placebo

### Recruitment centers

#### 1

##### Recruitment center

###### Name of recruitment center

Tehran Heart Center

###### Full name of responsible person

Zahra Alimohammad Ghelich Khan

###### Street address

Clinical Pharmacy Dept., School of Pharmacy, Tehran University of Medical Sciences

###### City

Tehran

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Masoud Yunesian

**Street address**

North Kargar-Ave

**City**

Tehran

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Tehran 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**

Tehran Heart Center

**Full name of responsible person**

Azita Hajhossein Talasaz

**Position**

Clinical Pharmacist

**Other areas of specialty/work**

**Street address**

Tehran, Tehran Heart Center

**City**

Tehran

**Postal code**

**Phone**

+98 21 8802 9610

**Fax**

**Email**

ahhtalasaz@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Azita Hajhossein Talasaz

**Position**

PhD

**Other areas of specialty/work**

**Street address**

clinical pharmacy department, school of pharmacy, Tehran university of medical sciences

**City**

tehran

**Postal code**

**Phone**

+98 21 8802 9256

**Fax**

**Email**

ahhtalasaz@yahoo.com

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

**Full name of responsible person**

Zahra Alimohammad Ghelich Khan

**Position**

**Other areas of specialty/work**

**Street address**

**City**

**Postal code**

**Phone**

+98 21 8840 0871

**Fax**

**Email**

z.gkhan@yahoo.com

**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*