

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Randomized trial of allopurinol in the prevention of pre-procedural myocardial injury in patients undergoing angioplasty

#### Protocol summary

##### Summary

Objective: To evaluate the effect of allopurinol on cardiac pre-procedural injury in patients undergoing angioplasty. Design: A prospective, single blinded, randomized controlled trial on patients with ischemic heart diseases who undergoing angioplasty. Setting and conduct: All patients with ischemic heart diseases who undergoing angioplasty in Shahid Madani Hospital will be randomized (using permuted block randomization, block size 2, allocation ratio 1:1) in two groups of allopurinol treated (n=50) and control (n=50). Participants: All consented patients with ischemic heart diseases aged 18-80 who undergoing angioplasty and stent insertion. The exclusion criteria will include elevation of CK-MB and cTnI before PCI, history of CABG during last three months, history of previous MI, renal dysfunction (creatinine above 2.5 mg/dl), unsuccessful PCI, acute MI, cardiogenic shock, dialysis, pregnancy, inability in filling and understanding of the consent form, unconsented patients, patients who want to discontinue the study at any time. Intervention: In allopurinol group, all patients will be received totally 1200 mg of oral allopurinol before PCI plus standard treatment. The control group will be received only standard treatment. Primary outcomes: Change of CK-MB and cTnI level 12 hours before, 8, and 24 hours after PCI in each groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201412088307N11**  
Registration date: **2017-07-04, 1396/04/13**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-07-04, 1396/04/13

##### Registrant information

###### Name

Taher Entezari-Maleki

###### Name of organization / entity

Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 6695 4709

###### Email address

tentezarimaleki@razi.tums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

##### Expected recruitment start date

2014-10-02, 1393/07/10

##### Expected recruitment end date

2015-03-19, 1393/12/28

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Randomized trial of allopurinol in the prevention of pre-procedural myocardial injury in patients undergoing angioplasty

##### Public title

Allopurinol in the prevention of pre-procedural myocardial injury following angioplasty

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria: Ischemic heart diseases patients; age 18-80; undergoing of angioplasty with stent insertion; filling of consent form. Exclusion Criteria: Elevation of CK-MB and cTnl before PCI; history of CABG during last three months; history of previous MI; renal dysfunction (creatinine above 2.5 mg/dl); unsuccessful PCI; acute MI; cardiogenic shock; dialysis; pregnancy; inability in filling and understanding of the consent form; unconsented patients; patients who want to discontinue the study at any time

#### Age

From **18 years** old to **80 years** old

#### Gender

Both

#### Phase

2-3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **100**

#### 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

Committee on Medical Ethics of Tabriz University of Medical Sciences

##### Street address

Golgasht Street

##### City

Tabriz

##### Postal code

-

#### Approval date

2014-09-29, 1393/07/07

#### Ethics committee reference number

93102

## Health conditions studied

### 1

#### Description of health condition studied

Ischemic heart diseases patients

#### ICD-10 code

I20, I21,

#### ICD-10 code description

Ischaemic heart diseases

## Primary outcomes

### 1

#### Description

CK-MB level

#### Timepoint

12 hours Before, 8 and 24 hours after angioplasty

#### Method of measurement

ELISA

### 2

#### Description

cTnl level

#### Timepoint

Before, 8 and 24 hours after angioplasty

#### Method of measurement

ELISA

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Control: In the control group, patients only will be given the standard treatment.

#### Category

N/A

### 2

#### Description

Intervention: In allopurinol group, all patients will be received totally 1200 mg before PCI plus the standard treatment.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Madani Heart Center of Tabriz

##### Full name of responsible person

Dr. Taher Entezari-Maleki

##### Street address

Shahid Madani Heart Center, Daneshgah Street

##### City

Tabriz

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Vice chancellor for research, Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad Reza Rashidi

**Street address**

Faculty of pharmacy, Daneshgah Street

**City**

Tabriz

**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, Tabriz 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**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Taher Entezari-Maleki

**Position**

Assistant professor/ Clinical pharmacist

**Other areas of specialty/work****Street address**

Daneshgah Street

**City**

Tabriz

**Postal code**

-

**Phone**

+98 41 3339 2593

**Fax**

-

**Email**

tentezari@gmail.com

**Web page address**

-

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Taher Entezari-Maleki

**Position**

Assistant professor/ Clinical pharmacist

**Other areas of specialty/work****Street address**

Daneshgah street

**City**

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## Person responsible for updating data

#### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

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Assistant professor/ Clinical pharmacist

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## 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*