

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### The impact of allopurinol versus placebo in patients with acute ST elevation myocardial infarction undergoing fibrinolytic therapy with streptokinase

#### Protocol summary

##### Summary

The impact of allopurinol versus placebo in patients with acute ST-elevation myocardial infarction undergoing fibrinolytic therapy with streptokinase is studied. One hundred and forty-six patients with first acute ST-elevation myocardial infarction and unavailable primary per-cutaneous coronary intervention, who are candidates for fibrinolytic therapy will be studied. Patients with previous myocardial infarction or primary valvular disease will be excluded from the study. Patients will be randomized (with Computer software "Random number generator"), double-blind (unaware patients and investigator) to placebo and allopurinol groups. In the Allopurinol group, patients will receive four oral Allopurinol 100mg tablets stat when arriving at the emergency department, followed by one 100mg tablet daily for 4 weeks, the other group will receive placebo. Then patients will be evaluated and compared for goals (90 minute ST resolution after fibrinolytic therapy, six months Major Adverse Cardiovascular Events (MACE), including in-hospital and late death, re-hospitalization for acute decompensation of heart failure, recurrent myocardial infarction and need to repeat revascularization).

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014062916229N3**  
Registration date: **2015-01-24, 1393/11/04**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-01-24, 1393/11/04

#### Registrant information

##### Name

Samad Ghaffari

##### Name of organization / entity

Cardiovascular Research Center, Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3333 3576

##### Email address

ghafaris@tbzmed.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Cardiovascular Research Center, Tabriz University of Medical Sciences  
Drug Applied Research Center, Tabriz University of Medical Sciences

#### Expected recruitment start date

2014-05-31, 1393/03/10

#### Expected recruitment end date

2015-05-31, 1394/03/10

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The impact of allopurinol versus placebo in patients with acute ST elevation myocardial infarction undergoing fibrinolytic therapy with streptokinase

#### Public title

The impact of Allopurinol in acute myocardial infarction

#### Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: Patients with first acute STEMI who are candidates for fibrinolytic therapy  
Exclusion criteria: Patients with first acute STEMI who are candidates for Primary PCI, Patients with previous myocardial infarction or Primary valvular disease

## Age

From **18 years** old to **90 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **146**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

The trial is double blind, so neither the patients nor the investigator are aware of the type of administered drug (Allopurinol or placebo). Random drug list has been prepared by the governing board of the Center for Drug Research.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

##### Street address

Tabriz University of Medical Sciences, Daneshgah St., Tabriz

##### City

Tabriz

##### Postal code

#### Approval date

2013-07-22, 1392/04/31

#### Ethics committee reference number

92178

## Health conditions studied

### 1

#### Description of health condition studied

myocardial infarction

#### ICD-10 code

121.3

#### ICD-10 code description

Acute transmural myocardial infarction of unspecified site

## Primary outcomes

### 1

#### Description

ST resolution (in millimeter)

#### Timepoint

On arriving at the emergency department (before the intervention) and 90 minute after streptokinase administration(intervention) in emergency department

#### Method of measurement

ECG

## Secondary outcomes

### 1

#### Description

Cardiac biomarkers level

#### Timepoint

first 48 hour (arrival at the emergency department (before the intervention) and then daily(after the intervention))

#### Method of measurement

laboratory

### 2

#### Description

Heart failure

#### Timepoint

During hospitalization

#### Method of measurement

Physical examination and history and echocardiography

### 3

#### Description

Recurrent myocardial infarction

#### Timepoint

six month after intervention (streptokinase)

#### Method of measurement

Telephone follow-up and patients hospital records

### 4

#### Description

In hospital death

#### Timepoint

During hospitalization

#### Method of measurement

Physical examination

## 5

### Description

six month death

### Timepoint

six month after intervention (streptokinase)

### Method of measurement

Telephone follow-up and patients hospital records

## 6

### Description

Re-hospitalization for acute decompensation of heart failure

### Timepoint

six month after intervention (streptokinase)

### Method of measurement

Telephone follow-up and patients hospital records

## 7

### Description

Repeat revascularization

### Timepoint

six month after intervention (streptokinase)

### Method of measurement

Telephone follow-up and patients hospital records

## Intervention groups

### 1

#### Description

Intervention 1: patients will receive four oral Allopurinol 100mg tablets when arriving at the emergency department, followed by one 100mg tablet daily for 4 weeks. Allopurinol is a xanthine oxidase inhibitor and decreases production of uric acid.

#### Category

Treatment - Drugs

### 2

#### Description

Intervention 2: Placebo tablets are similar in appearance with Allopurinol tablets, which patients will receive four oral tablets when arriving at the emergency department, followed by one tablet daily orally for 4 weeks. Allopurinol and Placebo tablets has prepared by Drug Applied Research Center of Tabriz University of Medical Sciences.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Cardiovascular Research Center

##### Full name of responsible person

Samad Ghaffari

#### Street address

Daneshgah Street, Shahid Madani Heart Hospital, Tabriz, Iran

#### 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

Samad Ghaffari

##### Street address

Cardiovascular Research Center, Daneshgah St., Tabriz

##### 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

Cardiovascular Research Center

##### Full name of responsible person

Samad Ghaffari

##### Position

MD

##### Other areas of specialty/work

##### Street address

Cardiovascular Research Center, Daneshgah St., Tabriz

##### City

Tabriz

##### Postal code

5166615573

##### Phone

+98 41 3337 3819

##### Fax

##### Email

ghafaris@gmail.com

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Cardiovascular Research Center of Tabriz University  
of Medical sciences

**Full name of responsible person**

Samad Ghaffari

**Position**

MD

**Other areas of specialty/work**

**Street address**

Cardiovascular Research Center, Daneshgah St.,  
Tabriz

**City**

Tabriz

**Postal code**

5166615573

**Phone**

+98 41 3335 7770

**Fax**

**Email**

ghafaris@gmail.com

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Cardiovascular Research Department, Tabriz  
University of Medical Sciences

**Full name of responsible person**

Samad Ghaffari

**Position**

MD

**Other areas of specialty/work**

**Street address**

Cardiovascular Research Center, Daneshgah St.,  
Tabriz

**City**

Tabriz

**Postal code**

5166615573

**Phone**

+98 41 3337 3819

**Fax**

**Email**

ghafaris@gmail.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*