

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 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

I21.3

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