

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Effect of high dose allopurinol on cardiac biomarkers (CTnT, CKMB) in patients undergoing elective percutaneous coronary intervention

Protocol summary

Summary

The aim of this randomized clinical trial study is evaluation of high dose allopurinol effect on cardiac biomarkers (CKMB, CTnT) and Malondialdehyde (oxidative stress marker) before and after elective PCI. All patients with coronary heart disease (based on coronary angiography) who are referred for elective PCI enrolled; and patients who are candidates for CABG or Primary PCI, Glomerular filtration rate less than 60 ml / min or serum creatinine more than 3 mg / dl, history of gout, taking allopurinol, severe liver disease, or concomitant use of azathioprine, 6 - mercaptopurine or warfarin will excluded. All patients after filing consent will be divided into two groups: 100 patients receiving allopurinol (intervention group) and 100 patients receiving placebo (control group). One day before and the day of PCI, allopurinol 600 mg orally will be given to intervention group and placebo to other group. Levels of cardiac biomarkers after PCI will also be assessed. Then, level of cardiac biomarkers in before and after PCI in both groups will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201210018698N1**

Registration date: **2012-11-03, 1391/08/13**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-11-03, 1391/08/13

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Tehran Heart Center. 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 high dose allopurinol on cardiac biomarkers (CTnT, CKMB) in patients undergoing elective percutaneous coronary intervention

Public title

Effect of allopurinol on cardiac biomarkers in patients undergoing elective percutaneous coronary intervention

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: patients who are candidates for elective PCI. Exclusion criteria: patients who are candidates for CABG or Primary PCI; Glomerular filtration rate less than 60 ml / min or serum creatinine more than

3 mg / dl; history of gout; taking allopurinol; severe liver disease; concomitant use of azathioprine, 6 - mercaptopurine or warfarin.

Age

No age limit

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)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran Heart Center Hospital

Street address

Tehran, Kargar-e- shomali st.

City

Tehran

Postal code

1411713138

Approval date

2012-08-16, 1391/05/26

Ethics committee reference number

319/ت م

Health conditions studied

1

Description of health condition studied

coronary artery disease

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease

Primary outcomes

1

Description

CTnT

Timepoint

before of intervention, one day after intervention

Method of measurement

ng/ml

2

Description

CKMB

Timepoint

before of intervention, one day after intervention

Method of measurement

ng/ml

Secondary outcomes

empty

Intervention groups

1

Description

Allopurinol 600 mg orally will be given to intervention group in two separated doses: first dose will be given one day before PCI and second dose given in the day of PCI.

Category

Treatment - Drugs

2

Description

Placebo orally will be given to control group in two separated doses: first dose will be given one day before PCI and second dose given in the day of PCI.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Heart Center Hospital

Full name of responsible person

Mohammad Javad Alemzadeh-Ansari

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences
Full name of responsible person
Fatemeh saaidi
Street address
16 Azar st, Tehran
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
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Person responsible for updating data

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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