

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

Effect of high dose of Allopurinol loading on level of inflammatory markers and in hospital composite events in Non ST-segment elevation myocardial infarction patients who refer to chamran hospital in Esfahan city.

Protocol summary

Study aim

Determination of the effect of high dose allopurinol on inflammatory markers and intra-hospital complications of the patients with acute myocardial infarction without ST elevation

Design

A double-blinded randomized clinical trial with parallel groups, with a control group

Settings and conduct

The current study will be conducted in the Specialized Cardiac center of Chamran in Isfahan during 2019-2021. In this study, the number of 40 patients will be treated with a loading dose of 600 mg of allopurinol before angiography and the latter 40 ones will be treated with a placebo. The patient's allocation to case or control group will be done using Random Allocation software in which each patient will be provided with a particular number to allocate him/her to one of the study groups. The researcher is not aware of the patient's treatment protocol and will be blinded. Besides, the groups will be shown as numbers 1 and 2 for the statistician and the statistician is blinded as well.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Typical chest pain for ischemia, Lacking ST-segment elevation in two adjacent leads, Seropositivity for cardiac troponin, The patient's willingness for participation in the study, The age range of 18-85 years old
Unmet criteria: Previous history of allopurinol administration, Cardiogenic shock, Grade III-IV of pulmonary edema, The diagnosis of ventricular tachycardia or ventricular fibrillation before the study

Intervention groups

The case group: treatment with loading dose of 600 mg allopurinol before angiography
The control group: treatment with placebo similar in shape, color, and size before angiography

Main outcome variables

Inflammatory biomarkers
Intra-hospital cardiac-related complications

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191223045866N1**

Registration date: **2020-02-28, 1398/12/09**

Registration timing: **registered_while_recruiting**

Last update: **2020-02-28, 1398/12/09**

Update count: **0**

Registration date

2020-02-28, 1398/12/09

Registrant information

Name

Ali Asadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3651 2852

Email address

asadiali.689@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-03-20, 1399/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of high dose of Allopurinol loading on level of inflammatory markers and in hospital composite events in Non ST-segment elevation myocardial infarction patients who refer to chamran hospital in Esfahan city.

Public title

Effect of Allopurinol in treatment of patients with Non ST-segment elevation myocardial infarction

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Ischemic type chest pain Non ST-segment elevation
Positive troponin biomarker Age of patient between 18-85

Exclusion criteria:

History of Allopurinol consumption Cardiogenic shock
Pulmonary edema with functional class III orIV
Ventricular tachycardia or ventricular fibrillation

Age

From **18 years** old to **85 years** old

Gender

Both

Phase

3

Groups that have been masked

- Investigator

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Each of the included patients will be provided a particular number allocated him/her to either treatment with allopurinol if the number is even or to placebo treatment if the number is odd.

Blinding (investigator's opinion)

Double blinded

Blinding description

The researcher is different from a person who provides the drugs to the patients, therefore the researcher is blinded to the type of medication. Besides, the groups will be provided to the statistician in codes 1 and 2; therefore the statistician is blinded to the treatment groups.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezarjarib Street

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Isfahan

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Isfahan

Postal code

8174673461

Approval date

2019-10-05, 1398/07/13

Ethics committee reference number

IR.mui.med.rec.1398.346

Health conditions studied**1****Description of health condition studied**

Acute myocardial infarction without ST segment elevation

ICD-10 code

I22

ICD-10 code description

Subsequent ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction

Primary outcomes**1****Description**

Inflammatory markers including highly sensitive C-reactive protein and highly sensitive cardiac troponin

Timepoint

Before the angiography and within 24 hours after acute myocardial infarction

Method of measurement

Blood sampling and laboratory assessment

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: 600 mg loading dose of allopurinol before angiography

Category

Treatment - Drugs

2**Description**

Control group: Treatment with placebo similar in shape, color and size before angiography

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Chamran Hospital

Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Esfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding*empty***Country of origin****Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Ali Asadi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Cardiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

the data of the current study are accessible in case of consent from the professor responsible for the study

When the data will become available and for how long

Following the publication of the manuscript the data are accessible

To whom data/document is available

The cardiologists who have similar proposal can access the data

Under which criteria data/document could be used

In cases of the consent from the professor responsible for the study and having related proposals

From where data/document is obtainable

To the professor responsible for the study

What processes are involved for a request to access data/document

An Email or telephoning to the professor responsible for the study

Comments