

# 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

**City**

Isfahan

**Province**

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**

Ali Asadi

**Street address**

Moshtagh Street

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3260 0965

**Email**

asadiali.689@gmail.com

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

Esfahan University of Medical Sciences

**Full name of responsible person**

Mojgan Mortazavi

**Street address**

Hezarjarib Street

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3792 9595

**Email**

mortazavi@med.mui.ac.ir

**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

**Street address**

7Aqiq, Ghadir Ave., Sepahan Shahr, Esfahan

**City**

Esfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3651 2852

**Fax****Email**

asadiali.689@gmail.com

**Person responsible for scientific 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

**Street address**

7Aqiq, Ghadir Ave., Sepahan Shahr, Esfahan

**City**

Esfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3651 2852

**Fax**

**Email**

asadiali.689@gmail.com

## Person responsible for updating data

### 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

**Street address**

7Aqiq, Ghadir Ave., Sepahan Shahr, Esfahan

**City**

Esfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3651 2852

**Fax**

**Email**

asadiali.689@gmail.com

## 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