

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

The Effect of High dose of Allopurinol loading on Percutaneous Coronary Intervention Outcomes and In-hospital Clinical Results in ST-segment Elevation Myocardial Infarction Patients; A Double-blind Randomized Clinical Trial

Protocol summary

Study aim

- To determine and compare coronary blood flow after high dose allopurinol loading in ST elevation myocardial infarction patients undergoing primary precancerous coronary intervention

Design

Two arm randomized parallel groups, double blind with control group

Settings and conduct

80 STEMI patients that candidate for primary or rescue PCI are selected according to the inclusion criteria and randomized to two equal groups by computerized method. In the case group, 600 mg of Allopurinol received before the intervention and the control group received placebo medication. After PCI, its results interpreted based on TIMI flow and MBG. Patients were also followed up during hospitalization for MACE and complications. intervening / interpreter and analyzer are blinded.

Participants/Inclusion and exclusion criteria

Entry: Acute STEMI below 24 hours for primary or rescue PCI
No entry: Routine PCI, STEMI over 24 hours, Previous consumption of Allopurinol or other anti-inflammatory drugs, Cardiac shock, Pulmonary edema with NYHA class 3/4, Any electrical and mechanical complications of STEMI

Intervention groups

Case group: 600 mg oral dose of Allopurinol before the intervention and immediately after arrival to emergency ward
Control group: placebo similar in shape and size with intervention group medication

Main outcome variables

Prescribing a loading dose of Allopurinol before the PCI can be used clinically and practically to achieve better PCI results in STEMI patients.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181228042155N1**

Registration date: **2019-07-13, 1398/04/22**

Registration timing: **registered_while_recruiting**

Last update: **2019-07-13, 1398/04/22**

Update count: **0**

Registration date

2019-07-13, 1398/04/22

Registrant information

Name

Mohammad Kermani-Alghoraishi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-22, 1398/04/01

Expected recruitment end date

2019-11-22, 1398/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of High dose of Allopurinol loading on Percutaneous Coronary Intervention Outcomes and In-hospital Clinical Results in ST-segment Elevation Myocardial Infarction Patients; A Double-blind Randomized Clinical Trial

Public title

The Effect of Allopurinol on Percutaneous Coronary Intervention Outcomes in ST-segment Elevation Myocardial Infarction Patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Acute ST-segment elevation MI Symptom onset below 24 hours PCI as primary or rescue approach

Exclusion criteria:

Acute STEMI onset more than 24 hours Candidate for routine PCI Previous consumption of Allopurinol and other anti-inflammatory medications Cardiac shock Pulmonary edema with NYHA class 3/4 Mechanical complications of acute STEMI Electrical complication of acute STEMI

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: 80

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done in simple way by computer. In fact, each patient's code is divided into a group at the beginning of the emergency ward by the computer.

Blinding (investigator's opinion)

Double blinded

Blinding description

- The physician conducting the intervention and interpreting the results of the PCI as well as the patient who follow-up patients during the hospitalization period are blind to the case and control groups. - The data analyzer is also blind to the groups.

Placebo

Used

Assignment

Parallel

Other design features

The first study to examine the effect of pre-intervention Allopurinol administration on PCI results in STEMI patients.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezar Jerib St, Isfahan University of Medical Sciences

City

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Province

Isfahan

Postal code

81746-73461

Approval date

2019-06-16, 1398/03/26

Ethics committee reference number

IR.MUI.MED.REC.1398.138

Health conditions studied

1

Description of health condition studied

Precancerous Coronary Intervention Outcome

ICD-10 code

I21

ICD-10 code description

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

Primary outcomes

1

Description

Coronary flow according to Thrombolysis In Myocardial Infarction (TIMI flow)

Timepoint

After precancerous coronary intervention

Method of measurement

Angioplasty videos interpretation

2

Description

Coronary flow according to Myocardial blush grade (MBG)

Timepoint

After precancerous coronary intervention

Method of measurement

Angioplasty videos interpretation

Secondary outcomes

1

Description

Post MI Electrical and Mechanical complication

Timepoint

During hospitalization

Method of measurement

Electrocardiography and Echocardiography

2

Description

Major Adverse Cardiac Events (MACE)

Timepoint

During hospitalization

Method of measurement

Questionnaire and physician interpretation

3

Description

Troponin level

Timepoint

Admission time and 48 hour after it

Method of measurement

Laboratory kit

4

Description

ECG changes

Timepoint

Admission time and after precancerous coronary intervention

Method of measurement

Objective interpretation

Intervention groups

1

Description

Intervention group: Received 600 mg Allopurinol loading before precancerous coronary intervention followed by 100 mg daily up to admission, Jalinous pharmaceutical Co.

Category

Treatment - Drugs

2

Description

Control group: Placebo

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Chamran Heart Center

Full name of responsible person

Mohammad Kermani-Alghoraishi

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Salman Farsi St., Shahid Chamran Heart Center

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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

Mohammad Kermani-Alghoraishi

Position

Associate professor

Latest degree

Specialist

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

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Patients data (Unidentifiable), Study protocol, Consent form, Clinical report will be reported in final paper

When the data will become available and for how long

Approximately 1 year after article printing

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

In order to complete further studies in this field

From where data/document is obtainable

Contact by email and phone with Dr. Mohammad Kermani-Alghoraishi sm.kermani@med.mui.ac.ir 0098 9133037414

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

The data is available about 1 year after the publication of the article in the scope mentioned above in order to complete further studies.

Comments