

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Evaluation of Allopurinol effect on Plasma Level of Cardiac Troponin-I and Creatine Kinase- MB in acute ischemic heart disease (ACS)

Protocol summary

Study aim

Evaluation Effects of Allopurinol on Plasma Level of Cardiac Troponin I and CK-MB Enzyme in ischemic heart patients.

Design

Randomised controlled clinical trial, Not blinded

Settings and conduct

This study is performed as a randomized clinical trial on 100 patients aged 18-80 years who have completed the ethical consent form and have been admitted to the emergency room of the Shahid Madani Research and Treatment Center in Tabriz with the diagnosis of acute coronary syndrome. In addition to routine treatment, patients in the intervention group receive allopurinol from Hakim Pharmaceutical Company. Patients in the control group receive only routine treatment. Blood levels of cardiac creatine kinase and cardiac troponin I in both groups are checked by ELISA.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with acute ischemic heart syndrome and 18-80 years old who have completed the form of ethical consent. Exclusion criteria: Serum creatinine above 2 mg per deciliter, unstable angina, persistent angina, history of dialysis and cardiogenic shock.

Intervention groups

Intervention group: In addition to routine treatment, patients receive oral administration of 600 mg of allopurinol Product of Hakim Pharmaceutical factory in two divided doses on the first day and then 300 mg of allopurinol daily for four days. Control group: will receive only routine treatment.

Main outcome variables

CTnI and CK-MB enzyme

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111206008307N36**

Registration date: **2020-07-28, 1399/05/07**

Registration timing: **retrospective**

Last update: **2020-07-28, 1399/05/07**

Update count: **0**

Registration date

2020-07-28, 1399/05/07

Registrant information

Name

Taher Entezari-Maleki

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-22, 1398/09/01

Expected recruitment end date

2020-05-19, 1399/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Allopurinol effect on Plasma Level of Cardiac Troponin-I and Creatine Kinase- MB in acute ischemic heart disease (ACS)

Public title

Evaluation of the effect of Allopurinol in reducing heart damage in acute ischemic heart patients

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients diagnosed with acute ischemic heart syndrome
Age 80-18 years Ability to understand and sign consent forms

Exclusion criteria:

Serum creatinine above 2 milligram Per deciliter Acute myocardial infarction History of dialysis Cardiogenic shock

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization was performed based on computer-generated random numbers list using online Graphpad randomizer software (<https://www.graphpad.com/quickcalcs/randMenu/>) and an allocation ratio of 1:1 in two intervention (group A) and control (Group B) with sample size n=100. After randomization 50 patients allocated in group A and the other 50 patients allocated in group B.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Tabriz University of Medical Sciences

Street address

Research and Technology Deputy, Tabriz University of Medical Science, Golgasht Street, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2019-07-18, 1398/04/27

Ethics committee reference number

TBZMED.REC.1398.424

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

Acute cardiac ischemic patients

ICD-10 code

I21.4

ICD-10 code description

Non-ST elevation (NSTEMI) myocardial infarction

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

Cardiac troponin I

Timepoint

Before, 8, 16, 24 and 32 hours after receiving allopurinol

Method of measurement

ELISA kits

2**Description**

Creatine Kinase-MB

Timepoint

Before, 8, 16, 24 and 32 hours after receiving allopurinol

Method of measurement

ELISA kite

Secondary outcomes

empty

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

Intervention group: After diagnosis of ischemic heart disease, patients receive 600 mg of allopurinol, product of Hakim Pharmaceutical factory, in two divided doses on the first day and then 300 mg of allopurinol daily for 4 days. Then the blood levels of cTnI and CK-MB are checked every 8 hours for 5 times by ELISA.

Category

Treatment - Drugs

2**Description**

Control group: Patients receive routine treatment after the diagnosis of ischemic heart disease. Blood levels of

the cTnI and CK-MB enzyme are checked every 8 hours for 5 times by ELISA.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Madani Heart Center of Tabriz

Full name of responsible person

Dr. Taher Entezari-Maleki

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Shahid Madani Heart Center, Daneshghah Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Web page address

<https://researchvice.tbzmed.ac.ir>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Taher Entezari-maleki

Position

Assistant Professor of Clinical Pharmacy

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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|

Person responsible for scientific inquiries

Contact

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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

Not applicable

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All of the data of an article can be published after making patients unrecognized

When the data will become available and for how long

After publishing of article until 6 months after publishing of the results

To whom data/document is available

Data will be available to researchers working in academic and scientific institutions

Under which criteria data/document could be used

Researchers that request data will be permitted only to doing analysis according to ethics for scientific aims

From where data/document is obtainable

Applicants can receive data by sending an E-mail to address of tentezari@gmail.com and get response from Dr. Taher Entezari Maleki

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

After contacting with corresponding author(Dr.Taher Entezari Maleki), data will be sent to Tabriz Shahid Madani hospital ethics committee and after receiving permission, data will be send to applicants

Comments