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

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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 infraction 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
Reasearch 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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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

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Latest degree

Ph.D.

Other areas of specialty/work

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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