

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 2026

Evaluation of the effect of metformin on cardiac troponin-I in STEMI patients treated with thrombolytic therapy

Protocol summary

Study aim

Evaluation of the effect of metformin on cardiac troponin-I in STEMI patients treated with thrombolytic therapy

Design

Randomized Control Trials, Double blind

Settings and conduct

This is a prospective, randomized controlled trial on a total of 80 consented patients older than 18 years with thrombolytic therapy who attended the Shahid Madani clinic of Tabriz University of Medical Science. intervention group will receive In addition to routine treatment, 1000 mg of metformin before thrombolytic. Patients in the control group will receive only routine treatment. The blood level of cTnI will be checked every 8 hours for 48_72 hours in two groups with and without metformin.

Participants/Inclusion and exclusion criteria

Inclusion: Ischemic heart diseases ; age 18-80; undergoing of thrombolytic therapy; filling of consent form
Exclusion: Elevation of troponin I- (above normal) at least 48 hours before thrombolytic therapy; history of CABG during last three months; history of previous MI; renal failure (creatinine clearance below 30 mg / dl or creatinine above 1 /4 in women and 1/5 in men); sensitivity to aspirin or clopidogrel and reteplase; cardiogenic shock; history of end-stage renal failure or dialysis; presence of metformin inhibition

Intervention groups

intervention group will receive In addition to routine treatment, 1000 mg of metformin before thrombolytic. Patients in the control group will receive only routine treatment.

Main outcome variables

Comparison of cTnI enzyme levels in STEMI patients in the two groups studied.

General information

Reason for update

The number of people decreased due to Corona virus.

Acronym

IRCT registration information

IRCT registration number: **IRCT20111206008307N34**
Registration date: **2020-06-02, 1399/03/13**
Registration timing: **registered_while_recruiting**

Last update: **2021-01-18, 1399/10/29**

Update count: **1**

Registration date

2020-06-02, 1399/03/13

Registrant information

Name

Taher Entezari-Maleki

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6695 4709

Email address

tentezarimaleki@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-05, 1398/10/15

Expected recruitment end date

2020-09-19, 1399/06/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of metformin on cardiac troponin-I in STEMI patients treated with thrombolytic therapy

Public title

Evaluation of the effect of metformin in STEMI patients treated with thrombolytic therapy

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Ischemic heart diseases age 18-80 undergoing of thrombolytic therapy filling of consent form

Exclusion criteria:

Elevation of troponin I- (above normal) at least 48 hours before thrombolytic therapy history of CABG during last three months history of previous MI; renal failure (creatinine clearance below 30 mg / dl or creatinine above 1 /4 in women and 1/5 in men) sensitivity to aspirin or clopidogrel and reteplase cardiogenic shock; history of end-stage renal failure or dialysis presence of metformin inhibition

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: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was done using computer generated random number (systematic randomization) by online Graphpad software by determining 2 study groups and 40 patients in each group (Control and Intervention) by an independent person.

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**

Ethic Committee of Tabriz Univercity of Medical Science

Street address

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

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2019-10-13, 1398/07/21

Ethics committee reference number

IR.TBZMED.REC.1398.713

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

Ischemic heart diseases patients

ICD-10 code

I20, I21,

ICD-10 code description

ischemic heart diseases

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

cTnl level

Timepoint

BASELINE,8,16, 24 AND 32 HOURS AFTER Thrombolytic

Method of measurement

ELISA

Secondary outcomes

empty

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

Intervention group: intervention group will recieve 1000 mg of metformin before thrombolytic with standard treatments

Category

Treatment - Drugs

2**Description**

Control group:Control group will only recieve standard treatments

Category

N/A

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

Shahid Madani Heart Center of Tabriz

Full name of responsible person

Dr. Taher Entezari-Maleki

Street address

Shahid Madani Heart Center, Daneshghah Street

City

Tabriz

Province

East Azarbaijan

Postal code

-

Phone

+98 41 3337 3901

Email

tentezari@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr.Mohammad Reza Rashidi

Street address

Daneshghah street,Golgasht

City

Tabriz

Province

East Azarbaijan

Postal code

3335710

Phone

+98 41 3335 7310

Email

tentezari@gmail.com

Web page address

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

Grant name

Grant code / Reference number

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

No

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/ Clinical pharmacist

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Daneshghah Street

City

Tabriz

Province

East Azarbaijan

Postal code

+98 41 3334 4798

Phone

+98 41 1339 2593

Fax

+98 41 1334 4798

Email

tentezari@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Taher Entezari-maleki

Position

Assistant professor/ Clinical pharmacist

Latest degree

Ph.D.

Other areas of specialty/work

Others

Street address

Faculty of pharmacy, Daneshgah Street

City

Tabriz

Province

East Azarbaijan

Postal code

+98 41 3334 4798

Phone

+98 41 1339 2593

Email

tentezari@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Taher Entezari-Maleki

Position

Assistant professor/Clinical pharmacist

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Email

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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