

# 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

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-

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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

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**Province**

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3335710

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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

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## Person responsible for scientific inquiries

#### Contact

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Ph.D.

**Other areas of specialty/work**

Others

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## Person responsible for updating data

#### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Taher Entezari-Maleki

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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**