

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Randomized trial of selenium in the prevention of pre-procedural myocardial injury in patients undergoing angioplasty

Protocol summary

Study aim

To evaluate the effect of selenium on cardiac pre-procedural injury in patients undergoing angioplasty.
Design: A prospective, single blinded, randomized controlled trial on patients with ischemic heart diseases who undergoing angioplasty

Design

Randomized Control Trials, Double blind

Settings and conduct

This is a prospective, randomized controlled trial on a total of 100 consented patients older than 18 years with angioplasty who attended the Shahid Madani clinic of Tabriz University of Medical Science. In selenium group, all patients will be received 1000 microgram selenase IV in normal salin serum half an hour before of angioplasty. The control group will be received only normal salin serum (pelacebo). Biochemical markers will be checked level 12 hours before, 8, and 24 hours after PCI in each groups.

Participants/Inclusion and exclusion criteria

Inclusion: Ischemic heart diseases and diabetic patients; age 18-85; undergoing of angioplasty with stent insertion; filling of consent form
Exclusion: Elevation of CK-MB and cTnl before PCI; history of CABG during last three months; history of previous MI; renal dysfunction (creatinine above 2.5 mg/dl); unsuccessful PCI; acute MI; cardiogenic shock; dialysis; pregnancy; inability in filling and understanding of the consent form; unconsented patients; patients who want to discontinue the study at any time.

Intervention groups

intervention group will receive 1000 microgram selenium dose with standard treatments control group will only receive standard treatments and placebo

Main outcome variables

Primary outcomes: Change of CK-MB and cTnl level 12 hours before, 8, and 24 hours after PCI in each groups

General information

Reason for update

Acronym

-

IRCT registration information

IRCT registration number: **IRCT20111206008307N30**

Registration date: **2018-12-27, 1397/10/06**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-27, 1397/10/06**

Update count: **0**

Registration date

2018-12-27, 1397/10/06

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

2018-09-23, 1397/07/01

Expected recruitment end date

2019-05-22, 1398/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Randomized trial of selenium in the prevention of pre-procedural myocardial injury in patients undergoing angioplasty

Public title

selenium in the prevention of pre-procedural myocardial injury in patients undergoing angioplasty

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Ischemic heart diseases and diabetic patients; age 18-85; undergoing of angioplasty with stent insertion; filling of consent form

Exclusion criteria:

Elevation of CK-MB and cTnI before PCI; history of CABG during last three months; history of previous MI; renal dysfunction (creatinine above 2.5 mg/dl); unsuccessful PCI; acute MI; cardiogenic shock; dialysis; pregnancy; inability in filling and understanding of the consent form; unconsented patients; patients who want to discontinue the study at any time.

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

-

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Randomization will be performed using permuted block randomization with a block size of 2 and an allocation ratio of 1:1 in two groups of Selenium and control.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Committee on Medical Ethics of Tabriz University of Medical Sciences

Street address

Golgasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

-

Approval date

2018-08-21, 1397/05/30

Ethics committee reference number

tbzmed.rec.1397.433

Health conditions studied

1

Description of health condition studied

Ischemic heart diseases patients

ICD-10 code

I20, I21,

ICD-10 code description

Ischaemic heart diseases

Primary outcomes

1

Description

CK-MB level

Timepoint

12 hours Before, 8 and 24 hours after angioplasty

Method of measurement

ELISA

2

Description

cTnI level

Timepoint

Before, 8 and 24 hours after angioplasty

Method of measurement

ELISA

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: intervention group will receive 1000 microgram selenium dose with standard treatments
control group will only receive standard treatments and placebo

Category

Treatment - Drugs

2

Description

Control group: In the control group, patients only will be given the standard treatment.

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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tentezari@gmail.com

Web page address

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

Faculty of pharmacy, Daneshgah Street

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Grant name

Grant code / Reference number

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

No

Title of funding source

Vice chancellor for research, 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

Others

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Person responsible for updating data

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

Not applicable

Title and more details about the data/document

Selenase in PMI

When the data will become available and for how long

After article publishing about 2 years after.

To whom data/document is available

All data of article.

Under which criteria data/document could be used

Based on publisher permission

From where data/document is obtainable

Based on publisher permission or may open access policy

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

Permission from corresponding or purchase the article or open access policy

Comments

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