Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 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.

Intervention groups

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

Main outcome variables

Primary outcomes: Change of CK-MB and cTnI 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)
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+98 21 6695 4709
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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 recieve 1000 microgram selenium dose with standard treatments control group will only recieve 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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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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Tabriz University of Medical Sciences

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Other areas of specialty/work
Others

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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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