

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### A Randomized trial of Co-Enzyme Q10 on Plasma Level of Cardiac Troponin-I and Creatinine Kinase- MB in patients undergoing to angioplasty and stenting.

#### Protocol summary

##### Summary

**Objective:** This study will be performed to evaluate the effect of Co-Enzyme Q10 in cardiac pre-procedural injury in patients undergoing angioplasty and stenting. **Design:** This is a prospective, randomized; controlled trial will perform on ischemic heart diseases patients undergoing angioplasty and stent insertion. **Setting and conduct:** All patients with ischemic heart diseases patients who undergoing angioplasty in Shahid Madani Hospital were randomized using permuted block randomization in two groups of Co-Enzyme Q10 treated and control. **Participants:** All consented patients with ischemic heart diseases aged 18-80 and undergoing of angioplasty and stent insertion will be entered. **Exclusion Criteria** will include elevation of CK-MB and cTnI 48 hours 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:** In Co-Enzyme Q10 group, all patients will receive totally 300 mg Co-Enzyme Q10 before PCI. In the control group, Co-Enzyme Q10 will not be administrated. **Primary outcomes** include comparison of blood level of CK-MB and cTnI 12 hours before and 8 and 24 hours after PCI in each group.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201311278307N3**  
Registration date: **2014-02-19, 1392/11/30**  
Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2014-02-19, 1392/11/30

##### Registrant information

###### Name

Taher Entezari-Maleki

###### Name of organization / entity

Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

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###### Email address

tentezarimaleki@razi.tums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice Chancellor for Research, Tabriz University Medical Sciences.

##### Expected recruitment start date

2014-02-20, 1392/12/01

##### Expected recruitment end date

2014-10-01, 1393/07/09

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

A Randomized trial of Co-Enzyme Q10 on Plasma Level of Cardiac Troponin-I and Creatinine Kinase- MB in patients undergoing to angioplasty and stenting.

##### Public title

Evaluation of Co-Enzyme Q10 in cardiac pre-procedural

injury of ischemic heart diseases patients undergoing angioplasty

### **Purpose**

Prevention

### **Inclusion/Exclusion criteria**

Inclusion criteria: ischemic heart diseases patients; Aged 18-80; undergoing of angioplasty; stent insertion; filling of consent form. Exclusion Criteria: elevation of CK-MB and cTnl 48 hours 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: **90**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Single blinded

### **Blinding description**

### **Placebo**

Not used

### **Assignment**

Parallel

### **Other design features**

In this study randomization was performed using permuted block randomization with a block size of 2 and an allocation ratio of 1:1 in two groups of Pentoxifylline and control.

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Tabriz Univrsity of Medical Sciences. Ethics committee.

##### **Street address**

Daneshghah Street

##### **City**

Tabriz

##### **Postal code**

#### **Approval date**

2013-11-18, 1392/08/27

#### **Ethics committee reference number**

92133

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Ischaemic heart diseases

#### **ICD-10 code**

I20-I25

#### **ICD-10 code description**

Ischaemic heart diseases

## **Primary outcomes**

### 1

#### **Description**

CK-MB level

#### **Timepoint**

12 hours before and 8 and 24 hours after angioplasty

#### **Method of measurement**

ELISA kits

### 2

#### **Description**

cTnl level

#### **Timepoint**

12 hours before and 8 and 24 hours after angioplasty

#### **Method of measurement**

ELISA kits

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention: In Co-Enzyme Q10 group, all patients will receive totally 300 mg Co-Enzyme Q10 before PCI.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control: In the control group, Co-Enzyme Q10 will not be administrated. two groups will be given standard treatment.

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Shahid Madani Hospital

##### **Full name of responsible person**

Dr.Taher Entezari Maleki

**Street address**

Daneshghah Street, Shahid Madani Heart Center

**City**

Tabriz

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Vice chancellor for research, Tabriz University of Medical Sciences.

**Full name of responsible person**

Dr.Mohammad Reza Rashidi

**Street address**

Daneshghah street

**City**

Tabriz

**Grant name**

-

**Grant code / Reference number**

-

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

Yes

**Title of funding source**

Vice chancellor for research, Tabriz University of Medical Sciences.

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

**Contact**

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Tabriz Universty of Medical Scienses.

**Full name of responsible person**

Dr. Taher Entezari-Maleki

**Position**

Assistant Professor of Clinical Pharmacy

**Other areas of specialty/work**

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr.Taher Entezari-Maleki

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Assistant Professor of Clinical Pharmacy

**Other areas of specialty/work**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*