

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jun 2026

Prospective evaluation of the effect of statin recapture on high sensitive troponin T and NGAL in elective PCI patients referred to Tehran Heart Center

Protocol summary

Summary

Objective: To determine the effect of statin recapture on high sensitive troponin T and NGAL in elective PCI patients referred to Tehran Heart Center Study design: Randomized, not blinded, no use of placebo, unicenter, phase IV trial Population: Inclusion criteria: candidate for Elective Percutaneous Coronary Intervention Exclusion criteria: High-Sensitivity Cardiac Troponin more than 24 NG/ML; Creatinine Clearance less than 30; Liver function test more than 3 times greater than normal; Ejection fraction less than 30 percent; Consumption of Amiodarone, Calcium channel blockers, Colchicine, and Digoxin Target sample size: 340 patients Intervention: - Atorvastatin, two 40 mg pills, 12 hours before PCI - Atorvastatin, 40 mg pill, 2 hours before PCI Primary outcome measures: -Serum high sensitive troponin T is measured by ELISA before and within 24 hours after PCI. - Urine NGAL is measured by ELISA before and 2 hours after PCI.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017011831073N2**

Registration date: **2017-05-02, 1396/02/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-05-02, 1396/02/12

Registrant information

Name

Hamidreza Poorhoseini

Name of organization / entity

Tehran University of Medical Sciences, Tehran Heart Center

Country

Iran (Islamic Republic of)

Phone

+98 21 8802 9721

Email address

porhosei@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences/ Tehran Heart Center

Expected recruitment start date

2016-08-22, 1395/06/01

Expected recruitment end date

2017-04-21, 1396/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Prospective evaluation of the effect of statin recapture on high sensitive troponin T and NGAL in elective PCI patients referred to Tehran Heart Center

Public title

Evaluation of the effect of very high dose atorvastatin on candidates for elective angioplasty

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: candidate for Elective Percutaneous Coronary Intervention Exclusion criteria: High-Sensitivity Cardiac Troponin more than 24 NG/ML; Creatinine

Clearance less than 30; Liver function test more than 3 times greater than normal; Ejection fraction less than 30 percent; Consumption of Amiodarone, Calcium channel blockers, Colchicine, and Digoxin

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **340**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Research Ethics Committee of Tehran University of Medical Sciences

Street address

16 Azar St, Enghelab Sq, Tehran Province

City

Tehran

Postal code

1417614418

Approval date

2017-03-01, 1395/12/11

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1395.1845

Health conditions studied

1

Description of health condition studied

Acute myocardial infarction after elective stenting, contrast-induced nephropathy after elective stenting

ICD-10 code

I25.1, I25

ICD-10 code description

Atherosclerotic heart disease, Old myocardial infarction

Primary outcomes

1

Description

Serum high sensitive troponin T

Timepoint

Before and within 24 hours after PCI

Method of measurement

ELISA

2

Description

Urine NGAL

Timepoint

Before and 2 hours after PCI

Method of measurement

ELISA

Secondary outcomes

empty

Intervention groups

1

Description

Intervention: Atorvastatin, two 40 mg pills, 12 hours before PCI and 40 mg atorvastatin 2 hours before PCI

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Heart Center

Full name of responsible person

Dr.Reza Lashkari

Street address

North Kargar Avenue

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Shahin Akhondzadeh

Street address

Room 302, first floor, Medical office building (number one), School of Medicine, Tehran University of Medical Sciences, Ebnesina street, 16 Azar street, Enghelab avenue, Enghelab square

City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source
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

2

Sponsor
Name of organization / entity
Tehran Heart Center
Full name of responsible person
Dr.Hamidreza Poorhosseini
Street address
Tehran Heart Center,North Kargar Avenue
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran Heart Center
Proportion provided by this source
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
Name of organization / entity
Tehran Heart Center
Full name of responsible person
Dr.Reza Lashkari
Position
Cardiologist.Interventional Cardiology Fellowship
Other areas of specialty/work
Street address
North Kargar Avenue
City

Tehran
Postal code
1411713138
Phone
+98 21 8802 9721
Fax
Email
rzlashkari@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran Heart Center
Full name of responsible person
Dr.Hamidreza Poorhosseini
Position
Assistance Professor of Interventional Cardiology
Other areas of specialty/work
Street address
North Kargar Avenue
City
Tehran
Postal code
1411713138
Phone
+98 21 8802 9721
Fax
+98 21 8802 9724
Email
porhosei@tums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Tehran Heart Center
Full name of responsible person
Dr. Reza Lashkari
Position
Cardiologist, Interventional Cardiology Fellowship
Other areas of specialty/work
Street address
North Kargar Avenue
City
Tehran
Postal code
1411713138
Phone
+98 21 8802 9721
Fax
Email
Rzlashkari@yahoo.com
Web page address

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