Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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)
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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 befor 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
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Tehran Heart Center,North Kargar Avenue
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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
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Person responsible for updating data

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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