Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effect of high dose atorvastatin within 24 hours before elective percutaneous coronary intervention on periprocedural myocardial infarction in patients treated at Imam Khomeini hospital between September 2010 to March 2010

Protocol summary

Summary

This study aimed to investigate the effect of high dose atorvastatin (80 mg) in reducing the Post-procedural MI following coronary angioplasty. In this triple-blind controlled randomized clinical trial, 190 adult candidates for elective PCI will be randomly assigned to receive high dose atorvastatin (80 mg) or placebo 24 hours before the procedure. Serum levels of creatinine kinase myocardial isoenzyme (CK-MB) and cardiac troponin I (cTNI) will be measured at baseline and then 6 and 12 hours following PCI to assess the incidence of MI. Post-procedural MI is defined as a CK-MB elevation >3 folds alone or associated with chest pain or ST segment or T wave abnormalities. In the statistical analysis, the relationship of myocardial infarction with the study variables and its incidence between the groups will be compared

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201205209768N1**
Registration date: **2012-08-16, 1391/05/26**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-08-16, 1391/05/26

Registrant information

Name

Akbar Shafiee

Name of organization / entity

Tehran Heart Center, Tehran University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Imam Khomeini hospital, Tehran University of Medical Sciences

Expected recruitment start date

2010-09-23, 1389/07/01

Expected recruitment end date

2011-03-20, 1389/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of high dose atorvastatin within 24 hours before elective percutaneous coronary intervention on periprocedural myocardial infarction in patients treated at Imam Khomeini hospital between September 2010 to March 2010

Public title

Effect of high dose atorvastatin in preventing myocardial infarction following coronary angioplasty

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Candidates for elective coronary

angioplasty with stable angina at Imam Khomeini hospital. Exclusion criteria:: 1- Previous CABG 2- Need for emergency primary PCI (<2 hours) 3- Renal dysfunction 4- Hypersensitivity to statins 5- History of PCI 6- Histoty of valvular disease (regurgitation =>3+ or stenosis > 2 cm2 7- serum creatinine > 1.2 mg/dl 8- History of liver dysfunction or rise of hepatic aminotransferases>3 folds 9- ejection fraction<30%

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **190**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Imam Khoemini hospital, tehran University of MEdical Sciences

Street address
Keshavarz Blvd, Dr. Gharib st.

City
Tehran

Postal code

Approval date
2010-05-28, 1389/03/07

Ethics committee reference number
23/586/89

Health conditions studied

1

Description of health condition studied
Acute Myocardial Infarction

ICD-10 code
I121

ICD-10 code description
Acute myocardial infarction

Primary outcomes

1

Description
Myocardial infarction

Timepoint
6 & 12 hours after angioplasty

Method of measurement
Serum levels of CK-MB and Troponin I

Secondary outcomes

empty

Intervention groups

1

Description
80 mg oral atorvastatin within 24 hours before PCI

Category
Treatment - Drugs

2

Description
80 mg oral placebo within 24 hours before PCI

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Khomeini hospital

Full name of responsible person
Reza Rahmani MD

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Keshavarz blvd, Dr. Gharib st

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Imam Khomeini hospital, Tehran University of MEdical Sciences

Full name of responsible person
Reza Rahmani

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Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Imam Khomeini hospital, Tehran 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
Name of organization / entity
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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