

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8802 9256

##### Email address

shafiee@leydenacademy.nl

##### 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- History 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 MEical 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

**Street address**

Keshavarz blvd, Dr. Gharib st

**City**

Tehran

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Imam Khomeini hospital, Tehran University of MEical  
Sciences

**Full name of responsible person**

Reza Rahmani

**Street address**

Keshavarz blvd, Dr. Gharib st

**City**

Tehran

**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**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Ali pasha Meisami  
**Position**  
Social and preventive medicine  
**Other areas of specialty/work**  
**Street address**  
Keshavarz blvd, Dr. Gharib st  
**City**  
Tehran  
**Postal code**  
**Phone**  
+216 6404377  
**Fax**  
**Email**  
meysamie@tums.ac.ir  
**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Imam Khoemini Hospital, Tehran University of medical sciences  
**Full name of responsible person**  
Reza Rahmani  
**Position**

Cardiologist  
**Other areas of specialty/work**  
**Street address**  
Keshavarz blvd, Dr. Gharib st  
**City**  
Tehran  
**Postal code**  
**Phone**  
+216 6404377  
**Fax**  
**Email**  
r\_rahmani@tums.ac.ir  
**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Latifeh Nafasi  
**Position**  
Resident of Cardiology  
**Other areas of specialty/work**  
**Street address**  
Keshavarz blvd, Dr. Gharib st  
**City**  
Tehran  
**Postal code**  
**Phone**  
+216 6404377  
**Fax**  
**Email**  
Latifehnafasi@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*