

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jun 2026

### Effect of atorvastatin on the incidence of atrial fibrillation in patients undergoing coronary artery bypass graft surgery

#### Protocol summary

##### Summary

One of the most prevalent complications of coronary artery bypass surgery (CABG) is atrial fibrillation (AF). The present study will be carried out to define the incidence of AF after CABG and the effect of perioperative use of statins on it. A total of 150 patients will be selected from patients undergoing isolated CABG surgery in two teaching hospitals of Shiraz University of Medical Sciences. Patients who have mixed cardiac operations including valve replacement and history of atrial fibrillation will be excluded. The study will be a randomized double-blind placebo-controlled trial. Patients will be randomized to receive atorvastatin 20 mg/d or placebo. The drug will be given 3 days before surgery and 5 days thereafter. In both groups, the incidence of AF after CABG will be assessed by ECG monitoring and compared using appropriate statistical tests.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138711131630N1**

Registration date: **2013-02-23, 1391/12/05**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2013-02-23, 1391/12/05

##### Registrant information

###### Name

Hossein Mirkhani

###### Name of organization / entity

Shiraz university of medical sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 1230 7591

###### Email address

mirkhanh@sums.ac.ir

###### Recruitment status

**Recruitment complete**

###### Funding source

Vice Chancellor for Research Affairs, Shiraz University of Medical Sciences

###### Expected recruitment start date

2012-04-07, 1391/01/19

###### Expected recruitment end date

2012-10-22, 1391/08/01

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

Effect of atorvastatin on the incidence of atrial fibrillation in patients undergoing coronary artery bypass graft surgery

###### Public title

Effect of atorvastatin on cardiac arrhythmias after open heart surgery

###### Purpose

Prevention

###### Inclusion/Exclusion criteria

Inclusion criteria: Patients undergoing isolated coronary artery bypass graft surgery. Exclusion criteria: 1. History of atrial fibrillation; 2. Renal failure with plasma creatinine greater than 2 mg/dl; 3. Malignant or inflammatory diseases; 4. Routine use of atorvastatin; 5. Mixed cardiac operations including valve replacement; 6. Using antiarrhythmic drugs except beta-blockers; 7. Active hepatic-biliary diseases; 8. Increase in serum

transaminases with undetermined cause; 9. Patients re-operated because of bleeding or other complications of surgery; 10. Glucocorticoids use.

#### **Age**

No age limit

#### **Gender**

Both

#### **Phase**

3

#### **Groups that have been masked**

No information

#### **Sample size**

Target sample size: **150**

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

Randomized

#### **Randomization description**

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

Double 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 Shiraz University of Medical Sciences

##### **Street address**

Zand Blvd. central building of Shiraz University of Medical Sciences

##### **City**

Shiraz

##### **Postal code**

#### **Approval date**

2011-10-06, 1390/07/14

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

CT-90-2692

## **Health conditions studied**

### **1**

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

Atrial fibrillation

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

I48

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

Atrial fibrillation and flutter

## **Primary outcomes**

### **1**

#### **Description**

Atrial fibrillation after Coronary Artery Bypass Graft surgery

#### **Timepoint**

During 5 days after operation

#### **Method of measurement**

ECG monitoring

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

Patients in case group will receive atorvastatin 20 mg, once daily 3 days before surgery, and 6 hours after extubation up to the day 5 after surgery. In the case of assisted respiration by ventilator, the drug will be administered through NG tube. All patients will receive beta blockers before surgery. During surgery, patient will be cooled to the 32 C, anesthetized with similar anesthetic agents and operated by an individual surgeon. All patients will be observed for the incidence of atrial fibrillation till discharge from hospital.

#### **Category**

Prevention

### **2**

#### **Description**

Patients in control group will receive placebo, once daily 3 days before surgery, and 6 hours after extubation up to the day 5 after surgery. In the case of assisted respiration by ventilator, the drug will be administered through NG tube. All patients will receive beta blockers before surgery. During surgery, patient will be cooled to the 32 C, anesthetized with similar anesthetic agents and operated by an individual surgeon. All patients will be observed for the incidence of atrial fibrillation till discharge from hospital.

#### **Category**

Placebo

## **Recruitment centers**

### **1**

#### **Recruitment center**

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

Namazi Teaching Hospital

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

##### **Street address**

##### **City**

Shiraz

**2**

**Recruitment center**

**Name of recruitment center**  
Shahid Faghihi Hospital  
**Full name of responsible person**  
**Street address**  
**City**  
Shiraz

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**  
Shiraz University of Medical Sciences  
**Full name of responsible person**  
Gholamreza Hatam  
**Street address**  
Zand Blvd.- central building of Shiraz University of  
Medical Sciences  
**City**  
Shiraz

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Shiraz 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**  
Shiraz University of Medical Sciences  
**Full name of responsible person**  
Hossein Mirkhani  
**Position**  
Associate professor of pharmacology  
**Other areas of specialty/work**  
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**Person responsible for scientific  
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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*

