

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
Street address
School of Medicine, Zand Blvd.
City
Shiraz
Postal code
Phone
+98 71 1230 7591
Fax
Email

mirkhanh@sums.ac.ir

Web page address

**Person responsible for scientific
inquiries**

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Hossein Mirkhani
Position
Ph. D. in Pharmacology
Other areas of specialty/work
Street address
School of Medicine, Zand Blvd.
City
Shiraz
Postal code
Phone
+98 71 1230 7591
Fax
Email
mirkhanh@sums.ac.ir
Web page address

Person responsible for updating data

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
Street address
School of Medicine, Zand Blvd.
City
Shiraz
Postal code
Phone
+98 71 1230 7591
Fax
Email
mirkhanh@sums.ac.ir
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

