Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparition of effect of high dose and low dose atorvastatin treatment on outcome of patients underwent CABG

Protocol summary

Summary

Comparition of effect of high dose and low dose atorvastatin treatment on outcome of patients underwent CABG. Randomized, double-blind, non-controlled with placebo, 100 patients undergoing CABG on-pump in Namazi hospital. Inclusion criteria: patients admitted in Nemazee hospital who underwent CABG on CPB; after learning of the investigation and completed an informed consent, were randomized to receive atorvastatin are divided into two groups. Exclusion criteria: unstable angina; myocardial infarction; evidence of recent MI (within 6 months); history of previous cardiac surgery; emergency surgery; congenital heart disease; a history of cardiac arrhythmias (Atrial Fibrilation) preoperatively received antiarrhythmic drugs (except Beta blocker); having Pacemaker; Left Ventricle Edjection Fraction less than 30%; uncontrolled hypertension; persistant atrial or ventricular arrhythmia; pregnant women; a history of diabet under treatment; elevated liver enzymes; renal failure with creatinine greater than 2mg/dl; inflammation or immune activation; muscle disease and alergy to statins. In cases 80 mg atorvastatin daily for 3 days before surgery and post-operative dose of 20 mg daily receives and controls 20 mg atorvastatin daily continuation different myocardial ischemia between the 2 groups by marker CK-MB and cardiac arrhythmias, blood glucose and kidney function in a variety of groups. CK-MB and C-reactive protein bifor induction,24 and 48 h after operation and blood suger before induction,in and after on-pump and each 6 h up to 48h and then daily in course of admission.Renal function tests befor surgery, day of 1 to 3 after operation and hematocrit befor,under and after on-pump and 3days after operation and LFT befor induction and second day after operation. 1month after surgery patients would be followed for cardiac function and myocardial infarction and need for revascularisation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012072310311N2**
Registration date: **2013-09-09, 1392/06/18**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-09-09, 1392/06/18

Registrant information

Name
Mohammad Bagher Khosravi
Name of organization / entity
Shiraz University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 71 1233 7636
Email address
khosravimb@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2013-08-23, 1392/06/01

Expected recruitment end date

2013-12-22, 1392/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparition of effect of high dose and low dose atorvastatin treatment on outcome of patients underwent CABG

Public title
Atorvastatin in open heart surgery

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria: patients admitted in Nemazee hospital who underwent CABG on CPB; after learning of the investigation and completed an informed consent, were randomized to receive atorvastatin are divided into two groups. Exclusion criteria: unstable angina; myocardial infarction; evidence of recent MI (within 6 months); history of previous cardiac surgery; emergency surgery; congenital heart disease; a history of cardiac arrhythmias (Atrial Fibrilation) preoperatively received antiarrhythmic drugs (except Beta blocker); having Pacemaker; Left Ventricle Edjection Fraction less than 30%; uncontrolled hypertension; persistant atrial or ventricular arrhythmia; pregnant women; a history of diabet under treatment; elevated liver enzymes; renal failure with creatinine greater than 2mg/dl; inflammation or immune activation; muscle disease and alergy to statins.

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shiraz University of Medical Sciences

Street address
the central building of shiraz University-zand street

City
shiraz

Postal code
71345-1978

Approval date
2013-08-04, 1392/05/13

Ethics committee reference number
CT-P-92-3628

Health conditions studied

1

Description of health condition studied
Coronary artery bypass graft

ICD-10 code
T82-2

ICD-10 code description
Mechanical complication of coronary artery bypass and valve grafts

2

Description of health condition studied
Diabet melitus

ICD-10 code
E10-11

ICD-10 code description
Insulin-dependent diabetes mellitus-Non-insulin-dependent diabetes mellitus

3

Description of health condition studied
Atrial fibrilation

ICD-10 code
I48

ICD-10 code description
Atrial fibrillation and flutter

4

Description of health condition studied
Deliriom

ICD-10 code
F05

ICD-10 code description
Delirium, not induced by alcohol and other psychoactive substances

5

Description of health condition studied
Acute myocardial ischemia and infarction

ICD-10 code
I21

ICD-10 code description
Acute myocardial infarction

Primary outcomes

1

Description
CK-MB
Timepoint
Befor induction, 24 and 48 h after surgery
Method of measurement
Labratory kit

2

Description
CRP
Timepoint
Befor induction, 24 and 48 h after surgery
Method of measurement
Laberatory kit

3

Description
Blood suger
Timepoint
Before induction, in pump, after off pump, every 6h upto48 h, then daily
Method of measurement
Glucometr

4

Description
Atrial fibrilation
Timepoint
During operation, in course of ICU admission
Method of measurement
Continioues ECG monitoring

5

Description
MACE(magor adverse cardiac events)
Timepoint
In ICU and up to 1 month after surgery
Method of measurement
Echocardiography

Secondary outcomes

1

Description
Ceratinin
Timepoint
Before surgery, daily up to 3 days
Method of measurement
Laberatory kit

2

Description
Hematocrit
Timepoint
Before surgery,in pump,off-pump,days of 1&2&3
Method of measurement
Laberatoty kit

3

Description
Liver function tests
Timepoint
Befor surgery,second day after operation
Method of measurement
Lab kit

4

Description
Delirium
Timepoint
In course of ICU admission
Method of measurement
Richmond scale daily

Intervention groups

1

Description
Patients in this study werw generally used 10 to 20 mg atorvastatin daily. Patients in this group, recived Atorvastatin 80 mg daily for 3 days before surgery and received postoperative low dose of 20 mg daily during the ICU stay
Category
Treatment - Drugs

2

Description
The control group received 20 mg atorvastatin daily and continues in ICU
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Namazi hospital
Full name of responsible person
Misagh Bastani. resident of anhesthesiology
Street address
Namazi Square, Zand street, Shiraz
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Gholamreza Hatam

Street address

Office of Research - Seventh Floor - Shiraz University of Medical Sciences - Central Building-zand street

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

Misagh Bastani

Position

Resident of anesthesiology

Other areas of specialty/work

Street address

Department of Anesthesiology-Operating room. namazi hospital

City

Shiraz

Postal code

7194714487

Phone

+98 71 1647 4270

Fax

Email

bastanim@sums.ac.ir; misaghbastani@ymail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mohamad Bagher Khosravi

Position

Associated professor

Other areas of specialty/work

Street address

Hengam Street. Lane 6/2. Last door on the right. Nyaysh Boulevard.Shiraz.

City

Shiraz

Postal code

Phone

+98 71 1654 1174

Fax

Email

khosravimb@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

Misagh Bastani

Position

Resident of anesthesiology

Other areas of specialty/work

Street address

Department of Anesthesiology.Namazi hospital.

City

Shiraz

Postal code

7194714487

Phone

+98 71 1627 0576

Fax

Email

bastanim@sums.ac.ir; misaghbastani@ymail.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