

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

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

Protocol summary

Summary

Comparison 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 Fibrillation) preoperatively received antiarrhythmic drugs (except Beta blocker); having Pacemaker; Left Ventricle Ejection Fraction less than 30%; uncontrolled hypertension; persistent atrial or ventricular arrhythmia; pregnant women; a history of diabetes under treatment; elevated liver enzymes; renal failure with creatinine greater than 2mg/dl; inflammation or immune activation; muscle disease and allergy 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 before induction, 24 and 48 h after operation and blood sugar before induction, in and after on-pump and each 6 h up to 48h and then daily in course of admission. Renal function tests before surgery, day of 1 to 3 after operation and hematocrit before, under and after on-pump and 3 days after operation and LFT before induction and second day after operation. 1 month 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

Comparison 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 Fibrillation) preoperatively received antiarrhythmic drugs (except Beta blocker); having Pacemaker; Left Ventricle Ejection Fraction less than 30%; uncontrolled hypertension; persistent atrial or ventricular arrhythmia; pregnant women; a history of diabetes under treatment; elevated liver enzymes; renal failure with creatinine greater than 2mg/dl; inflammation or immune activation; muscle disease and allergy 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 fibrillation

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

Before induction, 24 and 48 h after surgery

Method of measurement

Laboratory kit

2

Description

CRP

Timepoint

Before induction, 24 and 48 h after surgery

Method of measurement

Laboratory kit

3

Description

Blood sugar

Timepoint

Before induction, in pump, after off pump, every 6h upto 48 h, then daily

Method of measurement

Glucometer

4

Description

Atrial fibrillation

Timepoint

During operation, in course of ICU admission

Method of measurement

Continuous ECG monitoring

5

Description

MACE (major 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

Laboratory kit

2

Description

Hematocrit

Timepoint

Before surgery, in pump, off-pump, days of 1&2&3

Method of measurement

Laboratory kit

3

Description

Liver function tests

Timepoint

Before 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 were generally used 10 to 20 mg atorvastatin daily. Patients in this group, received 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 anesthesiology

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@gmail.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@gmail.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