Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Jul 2026

Comparison of Preconditioning Effect of High Dose and Low Dose Atorvastatin Treatment in Patients Underwent CABG

Protocol summary

Summary

Objective: Comparison of the Preconditioning Effect of High Dose and Low Dose of Atorvastatin in CABG. Study design: Triple-blind, randomized, clinical trial. Method:100 Patients who were undergoing on-pump coronary artery bypass graft (CABG) divided into two groups of A and B. 50 patients assigned in the intervention group and 50 patients in the control group. Inclusion criteria: Patients who had been taking (atorvastatin 20 mg daily) at least one year prior to the cardiac surgery. Exclusion criteria: Unstable angina; evidences of recent MI (within 6 months) ; history of cardiac surgery; congenital heart disease; history of cardiac arrhythmias (arterial fibrillation) before surgery; receiving anti- arrhythmic drugs (except Beta blockers) ; having pacemaker; left ventricle ejection fraction less than 30%, uncontrolled hypertension; arterial or ventricular arrhythmia; pregnancy; patient who are undergoing diabetes treatment; increased level of liver enzymes; renal failure with creatinine more than 2 mg/dl; active inflammation or immune deficiency; positive history of muscle disease or reaction to the stations. Intervention: Patients in the study group received 80 mg atorvastatin daily, for 3 days before surgery and low dose of 20 mg atorvastatin daily during the ICU stay, after surgery, and after discharge, the treatment continued at home with a single dose of 20 mg atorvastatin daily. On the other side, patients in the control group received 20 mg atorvastatin up to surgery and during the one month follow up period, they continued their medication with 20 mg atorvastatin daily. While, single dose of atorvastatin was given to the patients every night, an hour after the meal. The primary outcomes: troponin I, creatinine kinase-MB (CK-MB) and high-sensitivity C-reactive protein (hs-CRP) levels, the incidence of postoperative arrhythmia and ventricular fibrillation, mechanical ventilation duration in the ICU. Secondary outcomes: DC shock frequency, ICU length of stay, ejection fraction level, ICU blood intake, need for inotrope at the pomp off time or in the ICU, blood glucose, liver status glomerular filtration rate (GFR) and urine output.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017080619470N61**
Registration date: **2017-09-07, 1396/06/16**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-09-07, 1396/06/16

Registrant information

Name

Farzaneh Masihi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

masihif@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research ,Shiraz University of Medical Sciences

Expected recruitment start date

2013-04-21, 1392/02/01

Expected recruitment end date

2016-02-20, 1394/12/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of Preconditioning Effect of High Dose and Low Dose Atorvastatin Treatment in Patients Underwent CABG

Public title
Comparison of Preconditioning Effect of High Dose and Low Dose Atorvastatin Treatment in Patients Underwent CABG
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: patients who had been taking (atorvastatin 20 mg daily) at least one year prior to the cardiac surgery. Exclusion criteria: unstable angina; evidences of recent MI (within 6 months) ; history of cardiac surgery; congenital heart disease; history of cardiac arrhythmia (arterial fibrillation) before surgery; receiving anti- arrhythmic drugs (except Beta blockers) ; having pacemaker; left ventricle ejection fraction less than 30%, uncontrolled hypertension; arterial or ventricular arrhythmia; pregnancy; patient who are undergoing diabetes treatment; increased level of liver enzymes; renal failure with creatinine more than 2 mg/dl; active inflammation or immune deficiency; positive history of muscle disease or reaction to the stations.
Age
No age limit
Gender
Both

Phase
4
Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Triple blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
Randomization with Random Number Table

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences
Street address
Vice Chancellor of research, Shiraz University of Medical Sciences, 7th floor, central building of Shiraz University of Medical Sciences, Zand street
City
Shiraz
Postal code
Approval date
2010-09-23, 1389/07/01
Ethics committee reference number
CT-P-91-3628

Health conditions studied

1

Description of health condition studied
Coronary Artery Bypass Surgery
ICD-10 code
I25.1
ICD-10 code description
Atherosclerotic heart disease

Primary outcomes

1

Description
the serum level of CPK-MB enzymes, troponin I
Timepoint
before induction of anesthesia and 24 ,48 hours after surgery
Method of measurement
Arterial blood sample

2

Description
high-sensitivity C-reactive protein (hs-CRP) levels,
Timepoint
before induction of anesthesia and 24 ,48 hours after surgery
Method of measurement
Arterial blood sample

3

Description
mechanical ventilation duration in the ICU
Timepoint
After arrival to the ICU
Method of measurement
Observasion

Secondary outcomes

1

Description
glomerular filtration rate (GFR) and urine output
Timepoint
After surgery in the intensive care unit.
Method of measurement
observasion

2

Description
blood glucose
Timepoint
After surgery in the intensive care unit.
Method of measurement
blood sample

Intervention groups

1

Description
Patients in the study group received 80 mg atorvastatin daily, for 3 days before surgery and low dose of 20 mg atorvastatin daily during the ICU stay, after surgery, and after discharge, the treatment continued at home with a single dose of 20 mg atorvastatin daily.
Category
Treatment - Drugs

2

Description
patients in the control group received 20 mg atorvastatin up to surgery and during the one month follow up period they continued their medication with 20 mg atorvastatin daily.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Namazi Hosptioal
Full name of responsible person
Misagh Bastani
Street address
Namazi Hoptioal, Namazi Square
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Shiraz University of Medical Sciences
Full name of responsible person
Dr Seed Basir Hashemi
Street address
Vice chancellor of research,7th floor of central building of Shiraz University of Medical Sciences, 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
Vice Chancellor for Research, 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
anesthesiology resident/physician
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact
Name of organization / entity

Shiraz Universiy of Medical Sciences

Full name of responsible person

Mohammad Bagher Khosravi

Position

Cardio-anesthesiologist

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Farzaneh Masihi

Position

MS in english teaching ,BS in anesthesia/English Consultant

Other areas of specialty/work

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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

Data Dictionary

empty