

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

Comparison of the efficacy of Atorvastatin and Rosuvastatin in atrial fibrillation incidence after coronary artery bypass graft surgery (CABG)

Protocol summary

Study aim

Comparison of the efficacy of Atorvastatin and Rosuvastatin in atrial fibrillation incidence after coronary artery bypass graft surgery(CABG)

Design

Clinical trial with two parallel groups, double blind, randomised, phase 2 on 104 patients, in block randomization method with the size of 4 and 6, Random sequence will be generated by an epidemiologist by running an online program in sealed envelope website (<https://www.sealedenvelope.com/>).

Settings and conduct

The aim of the study is comparison of the efficacy of Atorvastatin and Rosuvastatin in reducing of atrial fibrillation incidence after coronary artery bypass graft surgery in 104 patients of Amiralmomenin hospital in Arak city. In first group Atorvastatin 40 mg tablet and in second group Rosuvastatin 20 mg tablet orally will be used after surgery when patient can use oral nutrition, daily for one week. Patients will be in group one or two, randomly.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All of patients referred to Amiralmomenin hospital for elective CABG surgery
Patients with 40 or more than 40 EF
Patients with On-pump method in surgery
Exclusion criteria: Recent MI
Using of antiarrhythmic drugs especially Amiodarone
History of AF
Valvular dysfunction
Other surgeries with CABG
Organic disease (i.e chronic renal failure stage 3 and 4), thyroid dysfunction, immunosuppression, cancer, central nervous system disease, brain vessels disease and history of CerebroVascular Accident, hormonal diseases, rise of liver enzymes)
Hypo/hyperkalemia
Dialysis (abnormal Cr)
Use of anti-inflammatory drugs
Psychological disorders

Intervention groups

In first group Atorvastatin 40 mg tablet and in second group Rosuvastatin 20 mg tablet orally will be used after surgery when patient can use oral nutrition, daily for one

week.

Main outcome variables

Frequency of post CABG atrial fibrillation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201028049175N2**

Registration date: **2021-01-13, 1399/10/24**

Registration timing: **prospective**

Last update: **2021-01-13, 1399/10/24**

Update count: **0**

Registration date

2021-01-13, 1399/10/24

Registrant information

Name

Shamim Valibak

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3417 3502

Email address

sh.valibak@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-10, 1399/12/20

Expected recruitment end date

2022-03-11, 1400/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the efficacy of Atorvastatin and Rosuvastatin in atrial fibrillation incidence after coronary artery bypass graft surgery (CABG)

Public title
Comparison of the efficacy of Atorvastatin and Rosuvastatin in atrial fibrillation incidence after coronary artery bypass graft surgery (CABG)

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
All of patients referred to Amiralmomenin hospital for elective CABG surgery Patients with 40 or more than 40 EF Patients with On-pump method in surgery
Exclusion criteria:
Recent MI Using of antiarrhythmic drugs especially Amiodarone History of AF Valvular dysfunction Other surgeries with CABG Organic disease (i.e chronic renal failure stage 3 and 4), thyroid dysfunction, immunosuppression, cancer, central nervous system disease, brain vessels disease and history of CerebroVascular Accident, hormonal diseases, rise of liver enzymes) Hypo/hyperkalemia Dialysis (abnormal Cr) Use of anti-inflammatory drugs Psychological disorders

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **104**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be allocated into two groups using a permuted balanced block randomization method with the size of blocks 4 and 6. Random sequence will be generated by an epidemiologist by running an online program in sealed envelope website (<https://www.sealedenvelope.com/>). Concealment is also guaranteed due to the use of specific codes that are obtained by the website.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients blindness: All patients are unaware about the name of drugs and the shape and size of drugs are similar. Researcher blindness: According to doctor's prescription, drugs will be given to the patients by nurses; so researcher's doctor filled the check lists is blind about the groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Arak University of Medical Sciences
Street address
Assistance of research and technology, Payambare azam institution, Arak University of Medical Sciences, Basij square
City
Arak
Province
Markazi
Postal code
3848176341

Approval date
2020-12-27, 1399/10/07

Ethics committee reference number
IR.ARAKMU.REC.1399.286

Health conditions studied

1

Description of health condition studied
Atrial fibrillation after CABG

ICD-10 code
I48.0

ICD-10 code description
Paroxysmal atrial fibrillation

2

Description of health condition studied
Atrial fibrillation after CABG

ICD-10 code
T82.9

ICD-10 code description
Unspecified complication of cardiac and vascular prosthetic device, implant and graft

Primary outcomes

1

Description
Frequency of post CABG atrial fibrillation

Timepoint
As starting drug till 7 days after surgery

Method of measurement

Heart monitoring

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group:Atorvastatin 40 mg tablet orally will be used after surgery when patient can use oral nutrition, daily till 7 days after surgery.

Category

Treatment - Drugs

2**Description**

Intervention group:Rosuvastatin 20 mg tablet orally will be used after surgery when patient can use oral nutrition, daily till 7 days after surgery.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Amiralmomenin hospital

Full name of responsible person

Alireza Rostami

Street address

Amiralmomenin hospital street, Basij square

City

Arak

Province

Markazi

Postal code

3848176941

Phone

+98 86 3417 3601

Email

it-amiralmomenin@arakmu.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Alireza Kamali

Street address

Assistance of research and technology, Payambare azam institution, Arak University of Medical Sciences, Basij square

City

Arak

Province

Markazi

Postal code

3848176341

Phone

+98 86 3417 3639

Email

research@arakmu.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Arak University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Alireza Kamali

Position

lecturer

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Valiasr hospital, Valiasr square

City

Arak

Province

Markazi

Postal code

3814957558

Phone

086-32222003-8

Email

alikalaliir@yahoo.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Elham Farahani

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Cardiology

Street address

Shahid Shiroudi street, Parastar square, Amirkabir hospital

City

Arak

Province

Markazi

Postal code

3814957558

Phone

08633134715-19

Email

farahani13025@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

shamim valibak

Position

General physician non-faculty

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Valiasr hospital, Valiasr square

City

Arak

Province

Markazi

Postal code

3814957558

Phone

086-32222003-8

Email

sh.valibak@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available