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 reffered 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 antiarhythmic 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 reffered 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 antiarhythmic 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
alikamaliir@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