Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jul 2026

Comparison of effects of atorvastatin and rosuvastatin in the prevention of atrial fibrillation in patients undergoing coronary artery bypass graft

Protocol summary

Study aim

Determination of the effects of atorvastatin in comparison with rosuvastatin in preventing AF rhythm in patients undergoing cardiovascular bypass surgery

Design

A randomized clinical trial study of 200 individuals randomly divided into two groups of 100, two arm parallel group with blinded postoperative care and outcome assessment

Settings and conduct

200 individuals who are candidates for Elective CABG in ShahidMadani Hospital in Tabriz are divided into 2 groups of 100.For one group atorvastatin 40 mg daily and for the other group rosuvastatin 20 mg daily from one week before CABG will be administrated,they will being under holter monitoring for 72 hours postoperatively. They will be also undergoing ECG until staying in the ward.For blinding, the drug given in 2 groups won't be labeled, and the patients will not be aware of their medication. Also,during the hospitalization of the patient,care staff and the person reporting the AF from Holter Monitoring won't be informed about the patient receiving the drug and the patient study group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Preoperative sinus rhythm,Patient consent,elective CABG surgery_Exclusion criteria:Urgent CABG,Previous cardiac surgery history,Cardiac surgery except CABG,left ventricle EF less than or equal to 25%,Left atrium size in echo more than 6 cm,Need to inotrope postoperatively,Being dependent on pacemaker after surgery,The patient's rhythm should not be sinus,Hyperthyroidism,valve insufficiency over than moderate in mitral and aortic valve ,Renal failure

Intervention groups

200 candidates for elective CABG will randomly divide into two groups of 100 . For one group atorvastatin 40 mg daily and for the other group rosuvastatin 20 mg daily one week before CABG will be prescribed.

Main outcome variables

Primary outcome: Determination of atrial fibrillation abundance after CABG surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191109045384N1**
Registration date: **2020-03-11, 1398/12/21**
Registration timing: **registered_while_recruiting**

Last update: **2020-03-11, 1398/12/21**
Update count: **0**

Registration date

2020-03-11, 1398/12/21

Registrant information

Name

Zahra Samadifar

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 41 3544 8657

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-20, 1397/12/01

Expected recruitment end date

2020-04-19, 1399/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of effects of atorvastatin and rosuvastatin in the prevention of atrial fibrillation in patients undergoing coronary artery bypass graft

Public title
Effects of atorvastatin and rosuvastatin on prevention of atrial fibrillation

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
The preoperative EKG of the patient must have sinus rhythm For the study, the patient must have satisfaction The patient must be a candidate for elective surgery The CABG surgery of the patient should be on pump

Exclusion criteria:
Urgent CABG surgery Previous cardiac surgery Cardiac surgery except CABG Left ventricular ejection fraction less than or equal to 25% Diameter of left atrium more than 6 cm in echocardiography Need to inotropic agents after surgery Being dependent on pace maker after surgery The patient's rhythm shouldn't be sinus. Hyperthyroidism Aortic and mitral valves disorder more than moderate Renal failure

Age
From **30 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **200**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be selected in two intervention (100 patients) and control (100 patients) groups. in this method with considering sample size, two colored cards (red and blue) with the equal quantity and the total sample size will be placed in a container. Then the qualified participants randomly will take one of the cards from the container and finally they will be entered in the atorvastatin or rosuvastatin groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
For blinding the study, drug given in two groups will be unlabeled, in which both drugs will be completely similar in color and form, and patients will not be aware of their medication. Also, during the hospitalization of the patient care, staffs and the person which will report the atrial fibrillation with Holter Monitoring won,t know about the patient's receiving drug and the patient's study group.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tbariz University of Medical Scinces

Street address
No. 27, Eighth of ten meters alley, University alley street, Attar neishabouri street

City
Tabriz

Province
East Azarbaijan

Postal code
5165938667

Approval date
2020-01-07, 1398/10/17

Ethics committee reference number
IR.TBZMED.REC.1398.1062

Health conditions studied

1

Description of health condition studied
Atrial fibrillation post coronary artery bypass graft

ICD-10 code
I48.0

ICD-10 code description
Paroxysmal atrial fibrillation

Primary outcomes

1

Description
Incidence rate of atrial fibrillation post coronary artery bypass graft

Timepoint
Holter monitoring for 72 hours and daily ECG for one week and if it continues after one week, daily ECG will be taken until discharge.(up to 1 month)

Method of measurement
Holter momitor and ECG devices

Secondary outcomes

1

Description
Incidence of diabetes and myopathy as possible complications of rosuvastatin.

Timepoint
Fasting blood glucose and creatine phosphokinase measurement and clinical examination at the end of the first week and then at the end of the first month and then six months later.

Method of measurement
Clinical examination and testing of fasting blood glucose and creatine phosphokinase

Intervention groups

1

Description
Intervention group: Administration of rosuvastatin (chemical formula (C22H27FN3O6S)2Ca) 20 mg / day (manufactured by Atiya Pharmaceutical New Technologies (FNDA)) one week before coronary artery bypass graft surgery in patients undergoing elective bypass surgery. Continuing of administration the drug until discharge and Holter monitoring during the first 72 hours after coronary artery bypass surgery (in the ICU ward) and taking daily ECG during admission in cardiology ward for up to one month and observation of changes.

Category
Prevention

2

Description
Control group:Administration of atorvastatin (chemical formula (C33H35FN2O5) 40 mg / day (manufactured by Atiya Pharmaceutical New Technologies (FNDA)) one week before coronary artery bypass graft surgery in patients undergoing elective bypass surgery. Continuing of administration the drug until discharge and Holter monitoring during the first 72 hours after coronary artery bypass surgery (in the ICU ward) and taking daily ECG during admission in cardiology ward for up to one month and observation of changes.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid madani hospital

Full name of responsible person
Zahra Samadifar

Street address
Daneshgah street, Shahid madani hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
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Attar neishaboori street,Tabriz University of Medical Sciences, Faculty of Medical Sciences

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Tabriz 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
Tabriz University of Medical Sciences

Full name of responsible person
Zahra Samadifar

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work

Cardiology
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No27,10th 8meters Block, Daneshgah Alley, Attar Neishabouri Street
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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
No - There is not 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