Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 2026

Comparison the effect of preoperative high dose and low dose rosouvastatin therapy on clinical outcomes after coronary artery bypass graft (CABG) surgery

Protocol summary

Study aim
Effect of high dose and low dose rosouvastatin on outcomes after coronary artery bypass graft (CABG) surgery

Design
This clinical trial will be conducted on 188 patients who are candidates for elective coronary artery bypass graft surgery. Patients were randomly divided into two equal size groups named group A (5 mg Ropixone) and group B (20 mg Ropixone) using Rand list software and based on quadruple random blocks (block random allocation). Ropixon is given daily from at least two days before surgery through one month after surgery. The study is double blind and the patient and investigator will be blinded. The trial phase is 3.

Settings and conduct
This study will be conducted as a double blind clinical trial in Dr.Heshmat hospital. The patient and investigator will be blinded and randomization will be done based on quadruple random blocks (block random allocation).

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients undergoing elective coronary artery bypass graft surgery. Exclusion criteria: Patients with atrial fibrillation, history of myocardial infarction.

Intervention groups
1: A; rosouvastatin (Ropixone) tablet 5 mg daily. 2: B; rosouvastatin (Ropixone) tablet 20 mg daily.

Main outcome variables
Atrial fibrillation; duration of hospitalization; mortality

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180113038329N1**
Registration date: **2018-05-01, 1397/02/11**
Registration timing: **registered_while_recruiting**

Last update: **2018-05-01, 1397/02/11**
Update count: **0**

Registration date
2018-05-01, 1397/02/11

Registrant information

Name
Mahdieh Sheikhi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 13 3366 9065

Email address
m_sheikhi@gums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-04-03, 1397/01/14

Expected recruitment end date
2018-06-04, 1397/03/14

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison the effect of preoperative high dose and low dose rosouvastatin therapy on clinical outcomes after coronary artery bypass graft (CABG) surgery

Public title
Effect of rosouvastatin in CABG

Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients undergoing elective CABG surgery
Exclusion criteria:
Patients with atrial fibrillation (AF) rhythm The current liver disease (illness) including liver Cirrhosis, blood transaminase increment by 3 or more, Blood bilirubin concentration greater than 3 mg / dl Recent use of antifungal medicines (azoles of CYP3A4 inhibitors), Protease inhibitor, Macrolides, Cyclosporine History of myocardial infarction Renal transplantation history Renal insufficiency (serum creatinine> 2.5 mg/dl) Cardiogenic shock Pregnancy Patients with complications during CABG surgery and after that (such as need for surgery for any reason, hemodynamic disorders, long intubation, rhythm disorders, need for shock, need for pericardiocentesis or chest tubing)
Age
From **18 years** old
Gender
Both

Phase
4
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **188**
More than 1 sample in each individual
Number of samples in each individual: **2**
Measuring hs CRP before and after coronary artery bypass graft surgery
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are randomly assigned to two groups of 94 people, using the Rand list software. The group A will receive rosouvastatin (Ropixon) 5 mg, the group B will receive rosouvastatin (Ropixon) 20 mg before surgery. Patients will be divided in two groups: A (low dose:5) and B (high dose:20), based on quadruple random blocks (block random allocation).
Blinding (investigator's opinion)
Double blinded
Blinding description
This study is double blind, and the patient and researcher will be blinded, the researcher will not know the dose of the patient's medication. The patient will not be aware of the dose of rosouvastatin. The individuals who are selected as followers during the hospitalization and one month after surgery will be blind. A cardiologist who is not included in the study will done the follow-up of patients without knowing the dose of rosouvastatin.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Guilan University of Medical Sciences
Street address
Research and Technology Deputy, Shahid Siyadati Ave., Namjoo Street
City
Rasht
Province
Guilan
Postal code
4144666949
Approval date
2017-12-16, 1396/09/25
Ethics committee reference number
IR. GUMS. REC. 1395.368

Health conditions studied

1

Description of health condition studied
Atrial fibrillation
ICD-10 code
I48.0
ICD-10 code description
Paroxysmal atrial fibrillation

Primary outcomes

1

Description
Atrial fibrillation
Timepoint
During the hospitalization period after coronary artery bypass graft surgery and one month later
Method of measurement
Cardiac monitoring, electrocardiogram

2

Description
hospitalization period
Timepoint
Duration of admission after coronary artery bypass graft surgery
Method of measurement
Number of admission days after coronary artery bypass graft surgery

3

Description
Mortality
Timepoint
During the hospitalization period after coronary artery bypass graft surgery and one month later
Method of measurement
Registration of death in the case during hospitalization after coronary artery bypass graft surgery and post-clearance follow up to one month

Secondary outcomes

1

Description
The incidence of myocardial infarction
Timepoint
During the hospitalization period after coronary artery bypass graft surgery until thirty days after that
Method of measurement
Electrocardiogram (ECG),serum cardiac enzymes level by biochemical method

2

Description
Changes of Ejection Fraction (EF)
Timepoint
Before performing coronary bypass graft surgery and thirty days after that
Method of measurement
Determine the percentage of Ejection Fraction (EF) by echocardiography

3

Description
High sensitivity C - Reactive Protein (hs_CRP) level
Timepoint
Before coronary artery bypass graft surgery and three days later
Method of measurement
Blood test, serum high sensitivity C - Reactive Protein (hs_CRP) level by Immunoturbidometry

4

Description
Acute renal failure
Timepoint
Two days after coronary artery bypass graft surgery
Method of measurement
blood test, serum creatinine level by biochemical method

5

Description
Stroke
Timepoint
Duration of hospitalization after coronary artery bypass graft surgery
Method of measurement
Based on patient's clinical symptoms and signs

6

Description
Total cholesterol changes
Timepoint
Before the coronary artery bypass graft surgery and thirty days after that
Method of measurement
blood test, serum total cholesterol level by biochemical method

7

Description
Triglyceride changes
Timepoint
Before the coronary artery bypass graft surgery and thirty days after that
Method of measurement
blood test, serum triglyceride levels by biochemical method

8

Description
Low Density Lipoprotein (LDL) cholesterol changes
Timepoint
Before the coronary artery bypass graft surgery and thirty days after that
Method of measurement
blood test, serum Low Density Lipoprotein (LDL) cholesterol levels by biochemical method

9

Description
High Density Lipoprotein (HDL) Cholesterol changes
Timepoint
Before the coronary artery bypass graft surgery and thirty days after that
Method of measurement
blood test, serum High Density Lipoprotein (HDL) Cholesterol levels by biochemical method

Intervention groups

1

Description
Intervention group 1: rosuvastatin tablet 5 mg once a day, starting at least two days before the coronary artery bypass surgery (CABG) and continuing until one month later.
Category
Treatment - Drugs

2

Description
Intervention group 2: rosuvastatin tablet 20 mg once a

day, starting at least two days before the CABG and continuing until one month later.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Dr. Heshmat Rasht Hospital

Full name of responsible person
Mahdieh Sheikhi

Street address
Dr. Heshmat Rasht Hospital, Bayani St., Valiasr Square

City
Rasht

Province
Guilan

Postal code
4193955588

Phone
+98 13 3366 9064

Fax
+98 13 3366 8718

Email
m_sheikhi@gums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Rasht University of Medical Sciences

Full name of responsible person
Shademan Neamati

Street address
Deputy of Research and Technology, Shahid Siadati Ave., Namjoo Street

City
Rasht

Province
Guilan

Postal code
4144666949

Phone
+98 13 3333 6394

Fax
+98 13 3333 6395

Email
gums.icrc@gmail.com

Grant name

Grant code / Reference number

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

Title of funding source
Rasht University of Medical Sciences

Proportion provided by this source
37

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
Other

2

Sponsor

Name of organization / entity
Dr. Abidi Pharmacy Company

Full name of responsible person
Amir Razavian Ardehali

Street address
Dr. Abidi Pharmaceutical Company, Dr. Abidi Blvd, 8th km of Karaj Special Road

City
Tehran

Province
Tehran

Postal code
76363 - 13897

Phone
+98 21 4454 2499

Fax

Email
info@doctor-abidi.com

Grant name

Grant code / Reference number

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

Title of funding source
Dr. Abidi Pharmacy Company

Proportion provided by this source
63

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact

Name of organization / entity
Rasht University of Medical Sciences

Full name of responsible person
Sheikhi Mahdieh

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Cardiology
Street address
Dr. Heshmat Hospital, Bayani St.,Valiasr Square
City
Rasht
Province
Guilan
Postal code
4193955588
Phone
+98 13 3366 9064
Email
gums.icrc@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Gholipoor Mahboobeh
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Cardiology
Street address
Doctor Heshmat hospital, Bayani alley, Moslla Square
City
Rasht
Province
Guilan
Postal code
4193955588
Phone
+98 13 3366 9064
Fax
+98 13 3366 8718
Email
gums.icrc@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Mahdieh Sheikhi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Cardiology
Street address
Doctor Heshmat hospital, Bayani alley, Moslla Square
City
Rasht
Province
Guilan
Postal code
4193955588
Phone
+98 13 3366 9064
Fax
+98 13 3366 8718
Email
m_sheikhi@gums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Information on the primary and secondary consequences
When the data will become available and for how long
6 to 12 months after printing results
To whom data/document is available
Researchers working in scientific and academic institutions
Under which criteria data/document could be used
Information on the main and secondary outcomes and the method of implementation and analysis and the results after approval by the scientific authority
From where data/document is obtainable
m_sheikhi@gums.ac.ir
What processes are involved for a request to access data/document
6 to 12 months after the publication of the results and also after examination by the scientific authority
Comments